



SGS

## VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE

No.: SHHL1602007536MD-01C  
Product Name: DISPOSABLE NITRILE GLOVE  
Style No: XS,S,M,L,XL,XXL  
Applicant: SHIJIAZHUANG HONGRAY GROUP CO.,LTD  
SOUTH TONGDA RD.,EAST DIST. JINZHOU CITY, HEBEI,  
052260, CHINA  
Manufacturer: SHIJIAZHUANG HONGRAY GROUP CO.,LTD  
SOUTH TONGDA RD.,EAST DIST. JINZHOU CITY, HEBEI,  
052260, CHINA  
Sufficient samples of the product have been tested and found to be in conformity with  
Test Standard: EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE-  
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM  
HOLES  
EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE-  
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL  
PROPERTIES  
EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE-  
PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL  
EVALUATION CLAUSE 4.4 & 4.6  
as shown in the  
Test Report Number(s): SHHL1602007536MD-01

This verification is only valid for the equipment and configuration described, and in conjunction with the test data detailed. It contains the result of the single examination of the subject being in hand and does not represent any universally valid decision concerning the quality of any subject of the current production.

Donna Gu  
CRS/Hardline SBU Section Head  
SGS-CSTC Standards Technical Services Co., Ltd.

Apr 12, 2016

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SGSPAPER  
16598818





## Test Report

No.: SHHL1602007536MD-01

Date: APR. 06, 2016

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SHIJIAZHUANG HONGRAY GROUP CO., LTD

SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1602007536MD  
DATE: MAR. 28, 2016

The following sample(s) was/were submitted and identified by the client as:

Sample Description : DISPOSABLE NITRILE GLOVE  
Style/ Item No. : XS,S,M,L,XL,XXL  
Country of Origin : CHINA  
Sample Receiving Date : FEB. 29, 2016  
Testing Period : FEB. 29, 2016 TO MAR. 28, 2016  
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT  
Test Requested : 1. EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE –  
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM  
FROM HOLES  
2. EN 455-2: 2015 MEDICAL GLOVES FOR SINGLE USE –  
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL  
PROPERTIES  
3. EN 455-3: 2015 MEDICAL GLOVES FOR SINGLE USE—  
PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL  
EVALUATION CLAUSE 4.4 & 4.6  
Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE  
FOLLOWING PAGE(S)  
Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

\*\*\*\*\*

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Vincent Feng  
Technical Manager



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## Test Report

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### Test Conducted:

#### 1. EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample : 200 Pieces  
 The type of gloves : examination/procedure gloves  
 Manufacturing batch code : /  
 Batch size : /  
 Sample size : XS, S, M, L, XL, XXL  
 Number of non-conforming gloves : None  
 Defects observed before testing : No defects  
 Test Result : Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing		# 1&2

#### 2. EN 455-2: 2015 Medical gloves for single use – part 2: Requirements and testing for physical properties

Number of test sample : 104 Pieces  
 Type : examination/procedure gloves  
 The manufacturing batch code : /  
 Size : XS, S, M, L, XL, XXL  
 Defects observed before testing : No defects  
 Test Result : Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#1&4
7	Labeling	Pass	/



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### 3. EN 455-3: 2015 Medical gloves for single use—Part 3: Requirements and testing for biological evaluation

Number of test sample : 5 Pieces  
 Finishes of gloves : Powdered-free gloves other than surgeon's gloves  
 Defects observed before testing : No defects  
 Test Result : Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1, 5&6
4.6	Labeling	Pass	/

#### Note:

- As per client's declare, these gloves (four size: XS, S, M, L, XL, XXL) only size different, the material is the same, and only the glove of size M was tested.
- See result 1.
- See result 2.
- See result 3.
- Test according to EN ISO 21171-2006.
- The powder of sample was  $0.3\text{mg} < 2\text{mg}$ .



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# Test Report

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## Test Results:

### 1. Watertightness test for detection of holes

Sample Quantity: 200pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

### 2. Dimensions

Sample Quantity: 78pcs

Size	XS												
Length(mm)	253	253	253	254	252	255	256	254	253	254	252	253	253
Width(mm)	79	78	79	77	78	77	78	77	78	79	78	79	78

Median value:

Length (mm): 253

Width (mm): 78

Size	S												
Length(mm)	245	244	242	243	244	246	245	244	245	246	244	243	243
Width(mm)	88	85	87	86	88	87	86	88	87	88	87	86	86

Median value:

Length (mm): 244

Width (mm): 87

Size	M												
Length(mm)	244	245	245	246	245	247	246	245	244	245	246	247	246
Width(mm)	96	95	97	96	95	97	96	96	95	96	97	96	97

Median value:

Length (mm): 245

Width (mm): 96

Size	L												
Length(mm)	243	242	241	242	243	242	242	242	242	243	241	242	243
Width(mm)	109	108	107	109	108	107	108	107	108	109	108	107	107

Median value:

Length (mm): 242

Width (mm): 108



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Size	XL												
Length(mm)	249	248	250	249	247	248	249	248	248	249	248	249	248
Width(mm)	114	113	114	115	113	114	115	115	114	115	116	114	115

Median value:

Length (mm): 248

Width (mm): 114

Size	XXL												
Length(mm)	245	246	244	244	245	246	245	246	246	245	245	244	243
Width(mm)	119	118	120	119	118	119	118	120	119	118	119	120	119

Median value:

Length (mm): 245

Width (mm): 119

Requirements: see table 1&2

**Table 1 Dimensions for surgical gloves**

Size	Median length in mm	Median width in mm
5	$\geq 250$	$67 \pm 4$
5.5	$\geq 250$	$72 \pm 4$
6	$\geq 260$	$77 \pm 5$
6.5	$\geq 260$	$83 \pm 5$
7	$\geq 270$	$89 \pm 5$
7.5	$\geq 270$	$95 \pm 5$
8	$\geq 270$	$102 \pm 6$
8.5	$\geq 280$	$108 \pm 6$
9	$\geq 280$	$114 \pm 6$
9.5	$\geq 280$	$121 \pm 6$

**Table 2 Dimensions for  
examination/procedure gloves**

Size	Median length in mm	Median width in mm
Extra small	$\geq 240$	$\leq 80$
Small		$80 \pm 10$
Medium		$95 \pm 10$
Large		$110 \pm 10$
Extra Large		$\geq 110$



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### 3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	9.19	8.79	9.27	9.02	8.25	9.35	9.27	9.36	8.98	8.38	9.02	8.90	9.58
Force at break after challenge testing(N)	9.41	9.50	9.50	9.38	9.58	9.46	9.23	9.38	9.77	9.50	9.58	9.18	9.65

Median value:

Force at break during shelf life (N): 9.02

Force at break after challenge testing (N): 9.50

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b) c)	
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).. c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			

Remark:

- The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.



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### Sample Photo:

Received sample (size XS)



Received sample (size S)



Received sample (size M)



Received sample (size L)



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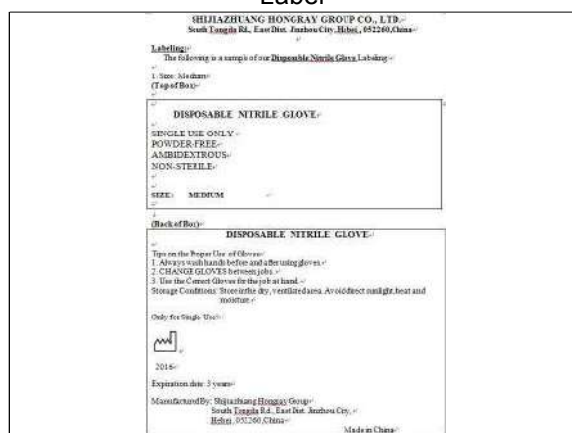
Received sample (size XL)



Received sample (size XXL)



Label



SGS authenticate the photo on original report only

\*\*\*End of Report\*\*\*

## Test Report

No. TSNEC2001185301

Date: 17 Jul 2020

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SHIJIAZHUANG HONGRAY GROUP CO., LTD.  
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI  
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE NITRILE GLOVE

SGS Job No. : TP20-004725 - TJ  
Date of Sample Received : 09 Jul 2020  
Testing Period : 09 Jul 2020 - 15 Jul 2020  
Test Requested : Selected test(s) as requested by client.  
Test Method : Please refer to next page(s).  
Test Results : Please refer to next page(s).

### Result Summary :

Test Requested	Conclusion
German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with amendments and BfR recommendation-Overall migration	PASS

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.



Reabeca Zhou  
Approved Signatory



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## Test Report

No. TSNEC2001185301

Date: 17 Jul 2020

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-011853.001	blue gloves	DISPOSABLE NITRILE GLOVE

Remarks :

- (1) mg/dm<sup>2</sup> = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C = degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected ( < MDL)

### German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with amendments and BfR recommendation-Overall migration

Test Method : With reference to EN1186-1:2002 for selection of conditions and test method;  
EN1186-3:2002 aqueous food simulants by total immersion method;

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Overall Migration	Conclusion
3% Acetic acid (W/V) aqueous solution	10minute(s)	40°C	50mg/dm <sup>2</sup>	<3.0mg/dm <sup>2</sup>	PASS

Notes :

- (1) Analytical tolerance of aqueous simulants is 1 mg/dm<sup>2</sup>
- (2) Category 1 contains commodities (articles and materials) which as a result of their intended use come into contact with foodstuffs for periods of between 24 hours and up to several months.
- (3) Category 2 contains commodities (articles and materials) that, when used as intended, come into contact with foodstuffs for no more than 24 hours.
- (4) Category 3 contains commodities (articles and materials) that, when applied as intended, come into contact with foodstuffs for no more than 10 minutes (short contact).
- (5) Special Category contains commodities intended for use as eating utensils or which may be expected to be placed in the mouth (e.g. toys).
- (6) The material category 3 was given by the client and not assessed by SGS
- (7) Report the first migration result.



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## Test Report

No. TSNEC2001185301

Date: 17 Jul 2020

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## Test Report

No. TSNEC2001185302

Date: 17 Jul 2020

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SHIJIAZHUANG HONGRAY GROUP CO., LTD.  
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI  
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE NITRILE GLOVE

SGS Job No. : TP20-004725 - TJ  
Date of Sample Received : 09 Jul 2020  
Testing Period : 09 Jul 2020 - 15 Jul 2020  
Test Requested : Selected test(s) as requested by client.  
Test Method : Please refer to next page(s).  
Test Results : Please refer to next page(s).

### Result Summary :

Test Requested	Conclusion
German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with amendments and BfR recommendation-Overall migration	PASS

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.



Reabeca Zhou  
Approved Signatory



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## Test Report

No. TSNEC2001185302

Date: 17 Jul 2020

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-011853.002	blue gloves	DISPOSABLE NITRILE GLOVE

Remarks :

- (1) mg/dm<sup>2</sup> = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected ( < MDL)

**German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with amendments and BfR recommendation-Overall migration**

Test Method : With reference to EN1186-1:2002 for selection of conditions and test method;  
EN1186-3:2002 aqueous food simulants by total immersion method;

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 002 Overall Migration	Conclusion
10% Ethanol (V/V) aqueous solution	10minute(s)	40°C	10mg/dm <sup>2</sup>	<3.0mg/dm <sup>2</sup>	PASS

Notes :

- (1) Analytical tolerance of aqueous simulants is 1 mg/dm<sup>2</sup>
- (2) Category 1 contains commodities (articles and materials) which as a result of their intended use come into contact with foodstuffs for periods of between 24 hours and up to several months.
- (3) Category 2 contains commodities (articles and materials) that, when used as intended, come into contact with foodstuffs for no more than 24 hours.
- (4) Category 3 contains commodities (articles and materials) that, when applied as intended, come into contact with foodstuffs for no more than 10 minutes (short contact).
- (5) Special Category contains commodities intended for use as eating utensils or which may be expected to be placed in the mouth (e.g. toys).
- (6) The material category 3 was given by the client and not assessed by SGS
- (7) Report the first migration result.



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Sample photo:



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## Test Report

No. TSNEC2001185303

Date: 17 Jul 2020

Page 1 of 3

SHIJIAZHUANG HONGRAY GROUP CO., LTD.  
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI  
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE NITRILE GLOVE

SGS Job No. : TP20-004725 - TJ  
Date of Sample Received : 09 Jul 2020  
Testing Period : 09 Jul 2020 - 15 Jul 2020  
Test Requested : Selected test(s) as requested by client.  
Test Method : Please refer to next page(s).  
Test Results : Please refer to next page(s).

## Result Summary :

Test Requested	Conclusion
Overall migration (as specified by clients)	PASS

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.



Reabeca Zhou  
Approved Signatory



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**Test Results :**

**Test Part Description :**

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-011853.003	blue gloves	DISPOSABLE NITRILE GLOVE

Remarks :

- (1)  $\text{mg}/\text{dm}^2$  = milligram per square decimeter
- (2)  $\text{mg}/\text{kg}$  = milligram per kilogram
- (3)  $^{\circ}\text{C}$  = degree Celsius
- (4)  $<$  = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected ( $<$  MDL)

**Overall migration (as specified by clients)**

Test Method : With reference to EN 1186-1:2002 for selection of conditions and test methods;  
or EN 1186-2:2002 olive oil by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 003 Overall Migration</u>
Olive Oil	10.0minute(s)	40°C	10mg/dm <sup>2</sup>	<3.0mg/dm <sup>2</sup>

Notes :

- (1) Analytical tolerance of fatty food simulants is 3 mg/dm<sup>2</sup>
- (2) Test condition & simulant were specified by client.
- (3) Report the first migration result.
- (4) The maximum permissible limit is quoted from the client requirements.



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Test Report

No. TSNEC2001185303

Date: 17 Jul 2020

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	<b>Material Safety Data Sheet</b>	Prepared Date:	2015.01.01
		Revision Times:	0

## SECTION 1: IDENTIFICATION

Product Name:	Nitrile Exam Gloves
Description:	Powder Free Nitrile Examination Gloves, Disposable Non-sterile, Blue
Product Use:	Intended for medical use; to be worn on the users hand to prevent contamination between patient and examiner.
Manufacturer:	Shijiazhuang Hongray Group Co., Ltd.
Telephone:	86-311-83980225
Fax:	86-311-83980221
Website:	<a href="http://www.hongray.com">www.hongray.com</a>

## SECTION 2: HAZARDOUS IDENTIFICATION

N/A

## SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Composition: *Mixture consisting of the following components*

IUPAC	SYNONYMS	MOLECULAR FORMULA	IDENTIFIERS
Nitrile gloves, and is mainly manufactured from Nitrile Latex (NBR), Potassium Hydroxide, Sulphur, Accelerator (such as ZDBC, ZMBT, and ZDEC etc), Zinc Oxide, Titanium Dioxide, Wingstay-L, Color Pigment (Blue)			

## SECTION 4: FIRST-AID MEASURES

Primary routes of entry: Eye and skin contact; ingestion; inhalation & skin absorption.  
Medical condition Aggravated by Exposure: Eyes/skin hypersensitivity

Eyes:	None known
Skin:	Under normal conditions, May not cause skin irritation.
Ingestion:	None known
Inhalation:	None known

## SECTION 5: FIRE FIGHTING MEASURES

General Information:	As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.
Flash Point:	No data available
Auto ignition Temperature:	No data available

	<b>Material Safety Data Sheet</b>	Prepared Date:	2015.01.01
		Revision Times:	0

Hazard Classification:	
Health:	Flammability:
Reactivity:	Special
Extinguishing Media:	Foam, Carbon Dioxide, Water
Special Fire Fighting Procedures:	No special requirement
Unusual Fire and Explosion Hazards:	N/A
Hazardous Decomposition Products:	No data available.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear appropriate personal protection during cleanup, such as impervious gloves.
Spill and Leak Procedures	N/A
Environmental Precautions	Package all material in appropriate container for disposal.

#### SECTION 7: HANDLING AND STORAGE

Handling & Storage:	Avoid ingestion and inhalation, change gloves between tasks
Other Precautions:	Store in cool and dry place

#### SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection:	Under normal handling conditions, a respirator may not be required.
Eye Protection:	Under normal handling conditions, safety glasses may not be required.
Skin Protection:	Change gloves between tasks
Engineering Controls:	N/A
Other Protective Clothing or Equipment:	N/A

#### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

pH:	>3.5,<9.5
Boiling Point:	No data available
Freezing Point:	No data available
Specific Gravity (H <sub>2</sub> O = 1):	No data available



	<b>Material Safety Data Sheet</b>	Prepared Date:	2015.01.01
		Revision Times:	0

Vapor Pressure (mm Hg):	No data available
Vapor Density (AIR = 1):	No data available
Evaporation Rate (Butyl Acetate = 1):	No data available
Solubility in Water:	Insoluble in water
Appearance and Odor:	Blue and no odor

#### SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable
Conditions To Avoid:	Keep away from heat, sparks and flame
Incompatibility (Material To Avoid)	
	Keep away and avoid mixing with prohibited substances (such as acid).
Hazardous Decomposition or By-products:	N/A
Hazardous Polymerization:	N/A

#### SECTION 11: TOXICOLOGICAL INFORMATION

Precautionary Statements:	
<u>Potential Health Effects:</u>	
Inhalation	No data available
Eye	No data available
Skin	The glove is evaluated not to be primary dermal irritant or sensitizer
Ingestion	No data available
Target Organs	No data available
Primary Routes of Exposure	Skin
Potential Effects of Chronic Exposure	Not available
Carcinogenicity	Not available
Irritation/Sensitization	Under normal conditions, the glove is evaluated not to be primary dermal irritant or sensitizer.
Teratogenicity	N/A
Mutagenicity	N/A
Reproductive Toxicity	N/A

	<b>Material Safety Data Sheet</b>	Prepared Date:	2015.01.01
		Revision Times:	0

<b>SECTION 12: ECOLOGICAL INFORMATION</b>	
Ecotoxicity	N/A
Biodegradability	N/A
Bioaccumulation	N/A
Mobility	N/A
Other Adverse Effects	N/A
<b>SECTION 13: DISPOSAL CONSIDERATIONS</b>	
Waste Disposal Method:	The user of this product must properly characterize the waste generated from the use of this product in accordance with all applicable federal, state and/ or local laws and regulations in order to determine the proper disposal of the waste in accordance with all applicable federal, state and/ or local laws and regulations.
<b>SECTION 14: TRANSPORT INFORMATION</b>	
Resource Conservation & Recovery Act (RCRA) Waste Number: Not available	
Basic Shipping Description:	Nitrile exam gloves
IATA	Not available
Proper Shipping Name:	Not available
Hazard Class:	Not available
Hazard Label:	Not available
Packing Group:	Not available
Packaging Instruction:	Not available
Special Provisions:	Not available
U.S. Department of Transportation (DOT) Consumer Commodity, ORM-D	
<b>SECTION 15: REGULATORY INFORMATION</b>	
US Federal Regulations:	
TSCA (Toxic Substance Control Act):	Not applicable
CERCLA/SARA - Hazardous Substances and their	Not applicable

	<b>Material Safety Data Sheet</b>	Prepared Date:	2015.01.01
		Revision Times:	0

Reportable Quantities:	
302 Extremely Hazardous Substances EPCRA RQs:	Not applicable
302 Extremely Hazardous Substances TPQs:	Not applicable
CERCLA/SARA - 313 - Emission Reporting:	Not applicable
US State Regulations:	
California - 8 CCR Section 339 - Director's List of Hazardous Substances	Not applicable
International Regulations:	
Water Hazard Class (Germany):	Not applicable
Canada	
Domestic Substances List (DSL)	Not applicable
WHMIS - Classifications of Substances	Not applicable
WHMIS - Ingredient Disclosure List	Not applicable
WHMIS Status	Not applicable
<b>SECTION 16: OTHER INFORMATION</b>	
No	

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# SHIJIAZHUANG HONGRAY GROUP CO., LTD

## Protocol for Shelf Life Determination Study

### 1.0 Purpose:

Conduct shelf life determination for Powder Free Nitrile Gloves, Blue as per EN455-4, so as to determine its shelf life.

### 2.0 Standard:

2.1 EN 455-4:2009: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

2.2 EN 455-1:2000: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

2.3 EN 455-2:2009: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

### 3.0 Samples Information:

Size: M

**Product Name:** Powder Free Nitrile Gloves, Blue

**Product Lot No. and quantity:** Random sample three production lots from production lines of Better Care Plastic Technology Co., Ltd. (10 cases per lot, and 1000 pieces/ case), conduct shelf life determination study per item 5.1-5.3.

### 4.0 Instruction of Sampling Testing:

According to EN455-1 and EN455-2, sample gloves individually from three production lots and conduct the following testing and record the testing data under the condition of time zero, accelerated aging determination.

Item		Criteria	Quantity and Acceptance Criteria
Length (mm)		≥240mm	13 pieces, median
Width (mm)		95±10mm	13 pieces, median
Thickness (mm)	Middle Fingertip $t_f$	$t_f/t_x \geq 0.9$	13 pieces
	Test piece $t_x$		
Force at Break (N)		≥6N	13 pieces, median
Watertightness		---	G-I, AQL1.5, sampling 80 pieces (Ac3, Re 4)

Notes:

1. Condition of sampling testing: Temperature: 23±2°C, Humidity: 50±5%
2. Samples shall be conditioned at least 16 hours before testing.

If all the testing results comply with the criteria requirements, and if the rate of change for the force at break tested exceed threshold value of 75% retained force at break, then the lot of products will be accepted. On the contrary, it will be rejected.

### 5.0 Shelf Life Determination Study:

#### 5.1 Time Zero Testing:

5.1.1 It is estimated to conduct time zero testing for gloves from March 27-31, 2013. The

testing will be conducted and recorded per item 4.0 after the randomly sampled gloves are conditioned. Analyze the testing data so as to ensure that original testing data for the gloves for shelf life determination comply with standard requirements.

5.1.2 If it is determined that the time zero testing result comply with standard requirements, start accelerated aging shelf life determination study and real time study.

## 5.2 Accelerated Aging Shelf Life Testing:

5.2.1 As per Annex B in EN 455-4, 4 different temperatures and 5 time point at each temperature are used for accelerated aging shelf life testing, and the testing is continued at least 180 days. The selected temperature and days are as follows:

# \ Temp	80°C	70°C	60°C	50°C
1	1 Day	1 Day	5 Days	22 Days
2	2 Days	3 Days	15 Days	35 Days
3	3 Days	7 Days	22 Days	55 Days
4	4 Days	8 Days	35 Days	90 Days
5	5 Days	10 Days	42 Days	110 Days

5.2.2 As per the arrangements in the above table, the schedule for each testing is as following:

Temp \ Testing Period	80°C	70°C	60°C	50°C
	Estimated testing period is: 2013.03.27-04.02	Estimated testing period is: 2013.04.03-04.14	Estimated testing period is: 2013.04.15-05.30	Estimated testing period is: 2013.06.01-09.20

5.2.3 Conduct accelerated aging for 3 lots of products at each selected temperature and time, and make relative testing and records as per item 4.0 after completing accelerated aging. Analyze and evaluate each testing data after each testing. If the rate of change for the force at break tested exceed threshold value of 75% retained force at break, then the lot of products will be accepted.

## 6.0 Standard for Shelf Life Determination

6.1 **Shelf life determination for accelerated aging shelf life testing:** After completing relative testing required in item 5.1 and 5.2, if each testing data comply with EN 455-1 and EN 455-2, and the rate of change for the force at break tested exceed threshold value of 75% retained force at break, then it is acceptable to claim that the shelf life of the gloves is 3 years.

## 7.0 Record and Files:

Details for shelf life determination study refer to corresponding testing report, and the testing data and report shall be filed permanently.

Prepared by: Xu Lihua/ QA Director of Better Care

Date: March 20, 2013

Reviewed by: Wymn/ QA Director of Hongray Group

Date: March 20, 2013



# SHIJIAZHUANG HONGRAY GROUP

## PERFORMANCE TESTING REPORT AT TIME ZERO

### **Purpose:**

As per EN455-4, carry out performance test at time zero to verify and determine whether the product of Powder Free Nitrile Gloves, Blue conform to associate standard requirements, and provide basic data for determining shelf life of the product.

**Date Tested:** March 27, 2013

### **Samples Tested:**

Gloves manufactured in current production lines of Better Care Plastic Technology Co., Ltd.

Machine No.: No. 6 and 7    Size: M  
Product Name: Powder Free Nitrile Gloves, Blue  
Product Lot No.: 130326061SA06  
                          130326072SA07  
                          130327072XA07

**Standards:** EN 455-4:2009 Medical Gloves for Single Use- Part 4: Requirements and Testing for Shelf life determination

The detailed testing results of the samples above-mentioned are as follows:

### **I. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 130326061SA06:**

#### **1. PERFORMANCE TESTING AT TIME ZERO----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 3.6N.

Conditioning: At least 16 hours

Tested by: Tao Ping

Song Ya

Test Condition: 23°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	96	5.8
2	M	245	0.08	0.12	95	5.9
3	M	241	0.08	0.11	95	5.7
4	M	243	0.08	0.11	95	5.8
5	M	244	0.08	0.11	95	5.9
6	M	245	0.08	0.11	95	6.5
7	M	246	0.08	0.11	95	6.4
8	M	243	0.08	0.11	95	6.2

9	M	245	0.08	0.11	95	6.2
10	M	245	0.08	0.12	96	6.3
11	M	246	0.08	0.11	95	6.3
12	M	243	0.08	0.11	95	6.0
13	M	245	0.08	0.11	95	6.4
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6.0\text{N}$ ).

## 2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

## 3. FINAL RESULTS of LOT NO. 130326061SA06:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## II. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 130326072SA07

### 1. PERFORMANCE TESTING AT TIME ZERO----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded results for force at break shall conform to the values of at least 3.6N.

Conditioning: At least 16 hours

Tested by: Tao Ping Song Ya Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	96	5.7
2	M	243	0.08	0.12	95	6.0
3	M	244	0.08	0.11	96	5.7
4	M	245	0.08	0.11	95	5.9
5	M	245	0.08	0.12	96	5.9
6	M	244	0.08	0.11	95	6.5
7	M	245	0.08	0.11	96	6.4
8	M	243	0.08	0.11	95	6.3
9	M	245	0.08	0.11	95	6.2
10	M	243	0.08	0.12	96	6.3
11	M	244	0.08	0.11	95	6.4
12	M	242	0.08	0.11	95	6.0



13	M	242	0.08	0.11	95	6.4
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6.0\text{N}$ ).

## 2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

## 3. FINAL RESULTS of LOT NO. 130326072SA07:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## III. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. LOT NO. 130327072XA07

### 1. PERFORMANCE TESTING AT TIME ZERO ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded results for force at break shall conform to the values of at least 3.6N.

Conditioning: At least 16 hours

Tested by: Tao Ping Song Ya Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.08	0.11	96	5.9
2	M	244	0.08	0.12	95	6.1
3	M	244	0.08	0.11	96	5.7
4	M	243	0.08	0.11	96	5.8
5	M	242	0.08	0.11	96	5.9
6	M	244	0.08	0.11	95	6.4
7	M	245	0.08	0.11	96	6.5
8	M	244	0.08	0.11	96	6.3
9	M	243	0.08	0.11	95	6.2
10	M	244	0.08	0.11	96	6.4
11	M	242	0.08	0.11	95	6.4
12	M	243	0.08	0.11	95	6.3
13	M	244	0.08	0.12	95	6.4
Median Value						6.3

It is showed from the above data that the performance testing of samples conform to the

specification (Force at Break  $\geq 6.0\text{N}$ ).

## 2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong      Zhao Sha      80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

## 3. FINAL RESULTS of LOT NO. 130327072XA07:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## IV. FINAL RESULT FOR PERFORMANCE TESTING AT TIME ZERO:

Through the performance test at time zero on 3 lots products(Lot No: 130326061SA06, 130326072SA07, 130327072XA07) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by:  QA Director of Better Care

Date: March 28, 2013

Reviewed by:  QA Director of Hongray Group

Date: March 28, 2013

# SHIJIAZHUANG HONGRAY GROUP

## PERFORMANCE TESTING REPORT AT 80°C FOR 5 TIME POINT

### **Purpose:**

As per EN455-4, carry out accelerated aging property test at 80°C for 5 time point (namely 1 day, 2 days, 3 days, 4 days, and 5 days) to verify and determine the shelf-life of Powder Free Nitrile Gloves, Blue.

**Date Tested:** March 27- April 2, 2013

### **Samples Tested:**

Gloves manufactured in current production lines of Better Care Plastic Technology Co., Ltd.

Machine No.: No. 6 and 7 Size: M

Product Name: Powder Free Nitrile Gloves, Blue

Product Lot No.: 130326061SA06  
130326072SA07  
130327072XA07

**Standards:** EN 455-4:2009 Medical Gloves for Single Use- Part 4: Requirements and Testing for Shelf life determination

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C OF LOT NO. 130326061SA06**

#### **1. Accelerated Aging Condition: 80°C@ 1 day      Conditioning: At least 16 hours**

#### **A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.07	0.12	95	5.9
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.4



5	M	244	0.08	0.11	95	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.07	0.11	96	6.4
8	M	243	0.08	0.11	96	5.9
9	M	241	0.08	0.12	95	6.0
10	M	242	0.08	0.11	96	6.2
11	M	240	0.08	0.11	95	6.6
12	M	241	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 2. Accelerated Aging Condition: 80°C @ 2 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.2
2	M	242	0.07	0.11	95	5.6
3	M	241	0.08	0.12	96	6.3
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	96	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.4

8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.0
10	M	241	0.08	0.11	95	6.2
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	6.0
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 2 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 3. Accelerated Aging Condition: 80°C @ 3 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	244	0.08	0.11	95	5.9
2	M	242	0.08	0.11	95	5.6
3	M	241	0.07	0.11	95	6.1
4	M	243	0.08	0.11	95	6.4
5	M	244	0.08	0.11	96	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.2
10	M	241	0.08	0.11	95	6.0

11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.12	96	6.5
13	M	240	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 3 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **4. Accelerated Aging Condition: 80°C @ 4 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.08	0.11	95	5.7
2	M	242	0.08	0.12	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	96	6.3
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.07	0.11	95	5.9
9	M	242	0.08	0.11	96	6.0
10	M	241	0.08	0.11	95	6.0
11	M	240	0.07	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8



Median Value	6.1
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It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 4 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 5. Accelerated Aging Condition: 80°C @ 5 days Conditioning: At least 16 hours

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.07	0.11	96	6.1
2	M	242	0.08	0.11	96	5.6
3	M	241	0.08	0.12	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	96	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.07	0.12	96	5.9
9	M	242	0.08	0.11	95	6.0
10	M	241	0.08	0.11	95	6.0
11	M	240	0.08	0.11	96	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 5 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 6. FINAL RESULTS of LOT NO. 130326061SA06:

Final performance-testing results of samples at conditions of 80°C@ 1 day, 80°C@ 2 days, 80°C@ 3 days, 80°C@ 4 days, 80°C@ 5 days conform to associate standard requirements, and can be used normally.

## II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C OF LOT NO. 130326072SA07

### 1. Accelerated Aging Condition: 80°C @ 1 day Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.07	0.12	96	5.7
2	M	242	0.08	0.11	95	5.9
3	M	241	0.08	0.11	96	6.1
4	M	240	0.08	0.11	95	6.4
5	M	244	0.08	0.11	95	6.3
6	M	242	0.08	0.11	96	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.07	0.12	95	5.9
9	M	242	0.08	0.11	96	6.0
10	M	241	0.08	0.11	95	6.2
11	M	240	0.08	0.11	96	6.6
12	M	243	0.08	0.11	96	6.4
13	M	242	0.08	0.11	95	6.3
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6\text{N}$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 2. Accelerated Aging Condition: 80°C @ 2 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.07	0.11	95	5.7
2	M	242	0.08	0.11	96	5.9
3	M	241	0.08	0.11	95	6.2
4	M	243	0.07	0.11	96	6.5
5	M	244	0.08	0.11	95	6.5
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.12	95	5.9
9	M	242	0.07	0.11	96	6.4
10	M	241	0.08	0.11	95	6.0
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.2
13	M	242	0.08	0.11	95	5.5
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6\text{N}$ ).



**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 &amp; EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C@ 2 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 80°C @ 3 days Conditioning: At least 16 hours****A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 &amp; EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.07	0.11	96	6.3
2	M	242	0.08	0.11	95	5.6
3	M	241	0.08	0.11	96	6.1
4	M	240	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.5
6	M	242	0.07	0.12	96	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.0
10	M	241	0.08	0.12	96	6.0
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 &amp; EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 3 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 4. Accelerated Aging Condition: 80°C @ 4 days Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.7
2	M	242	0.08	0.11	96	5.5
3	M	241	0.07	0.12	96	6.3
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.5
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.12	96	6.5
8	M	240	0.08	0.11	96	5.9
9	M	242	0.08	0.11	95	6.3
10	M	241	0.08	0.11	95	6.4
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.7
Median Value						6.3

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 4 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 80°C @ 5 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.7
2	M	242	0.08	0.11	95	5.8
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.4
6	M	240	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.6
9	M	242	0.08	0.11	95	6.0
10	M	241	0.08	0.11	95	6.5
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 5 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 130326072SA07:**

Final performance-testing results of samples at conditions of 80°C@ 1 day, 80°C@2 days, 80°C@ 3



days, 80°C@ 4 days, 80°C@ 5 days conform to associate standard requirements, and can be used normally.

### III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C OF LOT NO. 130327072XA07

#### 1. Accelerated Aging Condition: 80°C @ 1 day      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.07	0.11	95	6.0
2	M	242	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.12	96	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.07	0.11	96	6.5
8	M	240	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.0
10	M	241	0.08	0.11	95	6.0
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	96	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 80°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**2. Accelerated Aging Condition: 80°C @ 2 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.7
2	M	242	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.4
5	M	244	0.07	0.11	95	6.0
6	M	242	0.08	0.12	95	6.1
7	M	244	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	96	6.0
10	M	241	0.08	0.11	95	6.5
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	240	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 2 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 80°C @ 3 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.08	0.12	96	5.7
2	M	242	0.07	0.11	95	5.9
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.5
6	M	242	0.08	0.11	95	6.1
7	M	240	0.08	0.11	96	6.5
8	M	243	0.08	0.11	96	5.9
9	M	242	0.08	0.11	95	6.0
10	M	241	0.08	0.11	95	6.5
11	M	240	0.08	0.11	96	6.4
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

## B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

## C. TESTING RESULTS AT 80°C @ 3 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 4. Accelerated Aging Condition: 80°C @ 4 days      Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 51%



Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.9
2	M	240	0.08	0.11	95	5.6
3	M	241	0.07	0.11	96	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.12	95	6.3
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.4
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.5
13	M	242	0.08	0.11	96	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong      Zhao Sha      80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 80°C @ 4 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 5. Accelerated Aging Condition: 80°C @ 5 days      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.7
2	M	242	0.08	0.11	95	5.6

3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.0
10	M	241	0.08	0.11	95	6.0
11	M	240	0.08	0.11	95	6.6
12	M	243	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### **B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### **C. TESTING RESULTS AT 80°C @ 5 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **6. FINAL RESULTS of LOT NO. 130327072XA07:**

Final performance-testing results of samples at conditions of 80°C@ 1 day, 80°C@ 2 days, 80°C@ 3 days, 80°C @ 4 days, 80°C @ 5 days conform to associate standard requirements, and can be used normally.

#### **IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C:**

Through the accelerated aging performance test at 80°C@ 1 day, 80°C@ 2 days, 80°C @3 days, 80°C @ 4 days, 80°C @ 5 days on 3 lots products(Lot No: 130326061SA06, 130326072SA07, 130327072XA07) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by:  QA Director of Better Care

Date: April 03, 2013

Reviewed by:  QA Director of Hongray Group

Date: April 03, 2013

# SHIJIAZHUANG HONGRAY GROUP

## PERFORMANCE TESTING REPORT AT 70°C FOR 5 TIME POINT

### **Purpose:**

As per EN455-4, carry out accelerated aging property test at 70°C for 5 time point (namely 1 day, 3 days, 7 days, 8 days, and 10 days) to verify and determine the shelf-life of Powder Free Nitrile Gloves, Blue.

**Date Tested:** April 03-14, 2013

### **Samples Tested:**

Gloves manufactured in current production lines of Better Care Plastic Technology Co., Ltd.

Machine No.: No. 6 and 7 Size: M

Product Name: Powder Free Nitrile Gloves, Blue

Product Lot No.: 130326061SA06  
130326072SA07  
130327072XA07

**Standards:** EN 455-4:2009 Medical Gloves for Single Use- Part 4: Requirements and Testing for Shelf life determination

The detailed testing results of the samples above-mentioned are as follows:

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C OF LOT NO. 130326061SA06**

**1. Accelerated Aging Condition: 70°C@ 1 day      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties  
Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.7
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.0

6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.0
11	M	244	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **2. Accelerated Aging Condition: 70°C @ 3 days Conditioning: At least 16 hours**

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	5.7
2	M	240	0.08	0.11	95	5.9
3	M	241	0.08	0.11	96	6.4
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.0
6	M	242	0.08	0.11	95	6.2
7	M	240	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.07	0.12	96	6.2



10	M	240	0.08	0.11	95	6.3
11	M	242	0.08	0.11	95	6.5
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 3 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **3. Accelerated Aging Condition: 70°C @ 7 days      Conditioning: At least 16 hours**

### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.8
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.4
5	M	244	0.08	0.11	95	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.07	0.11	96	6.5
8	M	243	0.08	0.11	95	5.8
9	M	241	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.6
11	M	240	0.08	0.11	95	6.4
12	M	241	0.08	0.11	96	6.1

13	M	242	0.08	0.12	96	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 7 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **4. Accelerated Aging Condition: 70°C @ 8 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.08	0.11	95	5.5
2	M	240	0.08	0.12	95	5.6
3	M	241	0.07	0.11	95	6.1
4	M	243	0.08	0.11	96	6.5
5	M	244	0.08	0.11	95	6.3
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.08	0.11	95	6.4
10	M	241	0.08	0.11	95	6.0
11	M	245	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	241	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 &amp; EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 8 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 70°C @ 10 days Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 &amp; EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.7
2	M	240	0.07	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	96	6.5
5	M	244	0.08	0.11	95	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.0
11	M	240	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	241	0.08	0.11	96	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 &amp; EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 10 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 6. FINAL RESULTS of LOT NO. 130326061SA06:

Final performance-testing results of samples at conditions of 70°C@ 1 day, 70°C@ 3 days, 70°C@ 7 days, 70°C@ 8 days, 70°C@ 10 days conform to associate standard requirements, and can be used normally.

## II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C OF LOT NO. 130326072SA07

### 1. Accelerated Aging Condition: 70°C @ 1 day      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.07	0.12	96	6.3
2	M	241	0.08	0.11	95	5.7
3	M	241	0.08	0.11	95	6.3
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.2
6	M	242	0.08	0.12	96	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	242	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.0
11	M	240	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1



Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **2. Accelerated Aging Condition: 70°C @ 3 days      Conditioning: At least 16 hours**

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	5.7
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.12	95	6.2
6	M	242	0.07	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	243	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.0
11	M	247	0.08	0.12	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C@ 3 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 3. Accelerated Aging Condition: 70°C @ 7 days      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.07	0.12	96	5.7
2	M	240	0.08	0.11	95	5.7
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.0
6	M	242	0.08	0.11	96	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.3
11	M	240	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.9
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 7 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 70°C @ 8 days      Conditioning: At least 16 hours****A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 &amp; EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	5.7
2	M	240	0.08	0.11	96	5.9
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.3
6	M	242	0.08	0.11	95	6.2
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.08	0.11	96	6.4
10	M	244	0.08	0.11	95	6.0
11	M	240	0.08	0.12	95	6.6
12	M	240	0.07	0.11	96	6.2
13	M	243	0.08	0.11	95	5.8
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 &amp; EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 8 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 70°C @ 10 days      Conditioning: At least 16 hours****A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 &amp; EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.9
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.07	0.12	95	6.6
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.0
11	M	240	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 70°C @ 10 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 6. FINAL RESULTS of LOT NO. 130326072SA07:

Final performance-testing results of samples at conditions of 70°C@ 1 day, 70°C@3 days, 70°C@ 7 days, 70°C@ 8 days, 70°C@ 10 days conform to associate standard requirements, and can be used normally.

### III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C OF LOT NO. 130327072XA07

#### 1. Accelerated Aging Condition: 70°C @ 1 day      Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.



Tested by: Zhao Zhifen

Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.08	0.11	96	5.7
2	M	240	0.08	0.11	95	5.6
3	M	241	0.07	0.11	95	6.1
4	M	243	0.08	0.12	96	6.5
5	M	241	0.08	0.11	95	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.08	0.11	96	6.0
10	M	241	0.08	0.11	95	6.0
11	M	240	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **2. Accelerated Aging Condition: 70°C @ 3 days      Conditioning: At least 16 hours**

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.7
2	M	240	0.08	0.11	95	5.6

3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.2
6	M	242	0.08	0.11	95	6.1
7	M	241	0.07	0.12	96	6.5
8	M	243	0.08	0.11	95	5.9
9	M	241	0.08	0.11	95	6.0
10	M	240	0.08	0.11	96	6.4
11	M	240	0.08	0.11	95	6.6
12	M	241	0.08	0.11	96	6.5
13	M	242	0.08	0.11	95	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 3 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 3. Accelerated Aging Condition: 70°C @ 7 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	5.8
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.4
5	M	244	0.08	0.11	95	6.0

6	M	242	0.08	0.11	95	6.2
7	M	241	0.08	0.11	96	6.5
8	M	241	0.08	0.11	95	5.8
9	M	241	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.3
11	M	240	0.08	0.11	95	6.5
12	M	241	0.08	0.11	96	6.2
13	M	242	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 7 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 4. Accelerated Aging Condition: 70°C @ 8 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	96	5.7
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	96	6.5
5	M	244	0.08	0.11	95	6.0
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.9

9	M	241	0.07	0.11	95	6.0
10	M	240	0.08	0.11	96	6.0
11	M	240	0.08	0.11	95	6.6
12	M	241	0.08	0.12	96	6.1
13	M	242	0.08	0.11	95	5.8
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 8 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 5. Accelerated Aging Condition: 70°C @ 10 days Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 22, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.0
2	M	240	0.08	0.11	95	5.6
3	M	241	0.08	0.11	95	6.1
4	M	243	0.08	0.11	95	6.5
5	M	241	0.08	0.11	95	6.2
6	M	242	0.08	0.11	95	6.1
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.11	95	5.7
9	M	241	0.08	0.11	95	6.0
10	M	240	0.08	0.11	95	6.1
11	M	241	0.08	0.11	95	6.6
12	M	240	0.08	0.11	96	6.1



13	M	242	0.08	0.11	95	5.8
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### **B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### **C. TESTING RESULTS AT 70°C @ 10 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **6. FINAL RESULTS of LOT NO. 130327072XA07:**

Final performance-testing results of samples at conditions of 70°C@ 1 day, 70°C@ 3 days, 70°C@ 7 days, 70°C @ 8 days, 70°C @ 10 days conform to associate standard requirements, and can be used normally.

#### **IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C:**

Through the accelerated aging performance test at 70°C@ 1 day, 70°C@ 3 days, 70°C @7 days, 70°C @ 8 days, 70°C @ 10 days on 3 lots products(Lot No: 130326061SA06, 130326072SA07, 130327072XA07) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: Xu Lihua/ QA Director of Better Care

Date: April 14, 2013

Reviewed by: Wu Min/ QA Director of Hongray Group

Date: April 14, 2013

# SHIJIAZHUANG HONGRAY GROUP

## PERFORMANCE TESTING REPORT AT 60°C FOR 5 TIME POINT

### **Purpose:**

As per EN455-4, carry out accelerated aging property test at 60°C for 5 time point (namely 5 day, 15 days, 22 days, 35 days, and 42 days) to verify and determine the shelf-life of Powder Free Nitrile Gloves, Blue.

**Date Tested:** April 15-May 30, 2013

### **Samples Tested:**

Gloves manufactured in current production lines of Better Care Plastic Technology Co., Ltd.

Machine No.: No. 6 and 7 Size: M

Product Name: Powder Free Nitrile Gloves, Blue

Product Lot No.: 130326061SA06  
130326072SA07  
130327072XA07

**Standards:** EN 455-4:2009 Medical Gloves for Single Use- Part 4: Requirements and Testing for Shelf life determination

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C OF LOT NO. 130326061SA06**

**1. Accelerated Aging Condition: 60°C@ 5 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties  
Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	96	6.0
2	M	242	0.08	0.12	96	6.4
3	M	241	0.08	0.11	95	6.0
4	M	243	0.08	0.11	95	6.1
5	M	244	0.07	0.11	95	6.2
6	M	242	0.08	0.11	96	5.8

7	M	241	0.08	0.11	96	5.9
8	M	243	0.08	0.11	95	6.2
9	M	242	0.08	0.11	96	6.6
10	M	241	0.07	0.11	96	5.9
11	M	240	0.08	0.12	95	6.5
12	M	243	0.08	0.11	95	6.1
13	M	242	0.07	0.11	95	6.2
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 5 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **2. Accelerated Aging Condition: 60°C @ 15 days      Conditioning: At least 16 hours**

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.3
2	M	240	0.08	0.11	96	6.4
3	M	241	0.08	0.11	95	6.0
4	M	243	0.08	0.11	95	6.1
5	M	244	0.08	0.11	96	6.3
6	M	242	0.08	0.11	96	5.8
7	M	241	0.08	0.11	96	5.4
8	M	243	0.08	0.11	95	6.2
9	M	241	0.08	0.11	96	6.1
10	M	240	0.07	0.11	96	5.7

11	M	240	0.08	0.12	95	6.5
12	M	240	0.08	0.11	95	6.1
13	M	242	0.07	0.11	95	6.0
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 15 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **3. Accelerated Aging Condition: 60°C @ 22 days      Conditioning: At least 16 hours**

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	244	0.08	0.11	95	6.0
2	M	241	0.07	0.11	96	6.4
3	M	240	0.08	0.11	95	6.0
4	M	242	0.08	0.11	95	6.1
5	M	243	0.08	0.11	96	6.3
6	M	242	0.08	0.11	95	5.8
7	M	243	0.08	0.11	96	5.9
8	M	241	0.08	0.12	95	6.2
9	M	240	0.08	0.11	96	6.5
10	M	241	0.07	0.11	96	5.7
11	M	242	0.08	0.12	95	6.5
12	M	241	0.08	0.11	95	6.4
13	M	242	0.07	0.11	95	6.2

Median Value	6.2
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It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 4. Accelerated Aging Condition: 60°C @ 35 days Conditioning: At least 16 hours

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.2
2	M	241	0.08	0.11	96	6.2
3	M	243	0.08	0.11	95	6.0
4	M	242	0.07	0.12	95	6.1
5	M	240	0.08	0.11	96	6.3
6	M	241	0.08	0.11	95	5.6
7	M	242	0.08	0.11	96	5.9
8	M	243	0.08	0.11	95	6.5
9	M	241	0.08	0.11	96	6.4
10	M	242	0.07	0.11	96	5.7
11	M	242	0.08	0.12	95	6.5
12	M	241	0.08	0.11	95	6.1
13	M	244	0.07	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing



Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 35 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 5. Accelerated Aging Condition: 60°C @ 42 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 21°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.08	0.11	96	6.2
2	M	244	0.08	0.11	96	6.4
3	M	240	0.08	0.11	95	6.0
4	M	240	0.08	0.12	95	6.5
5	M	243	0.07	0.11	95	6.3
6	M	242	0.08	0.11	96	5.7
7	M	243	0.08	0.11	96	5.8
8	M	240	0.08	0.11	95	6.2
9	M	241	0.08	0.11	96	6.6
10	M	244	0.07	0.11	96	5.6
11	M	241	0.08	0.12	95	6.5
12	M	242	0.08	0.11	95	6.1
13	M	240	0.07	0.11	95	6.4
Median Value						6.3

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 42 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 6. FINAL RESULTS of LOT NO. 130326061SA06:

Final performance-testing results of samples at conditions of 60°C@ 5 days, 60°C@ 15 days, 60°C@ 22 days, 60°C@ 35 days, 60°C@ 42 days conform to associate standard requirements, and can be used normally.

## II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C OF LOT NO. 130326072SA07

### 1. Accelerated Aging Condition: 60°C @ 5 days Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.08	0.11	96	6.3
2	M	241	0.07	0.11	96	6.4
3	M	242	0.08	0.11	95	6.0
4	M	241	0.08	0.12	95	6.1
5	M	244	0.08	0.11	96	6.3
6	M	241	0.08	0.11	96	5.7
7	M	245	0.08	0.11	96	5.6
8	M	243	0.08	0.11	95	6.2
9	M	241	0.08	0.11	96	6.6
10	M	242	0.07	0.11	96	5.7
11	M	241	0.08	0.12	95	6.5
12	M	243	0.08	0.11	95	6.1
13	M	240	0.07	0.11	95	6.4
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
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Free from holes	M	80	0
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It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 5 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 2. Accelerated Aging Condition: 60°C @ 15 days      Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.08	0.11	96	6.4
2	M	241	0.07	0.11	96	6.4
3	M	242	0.08	0.11	95	6.5
4	M	244	0.08	0.11	95	6.1
5	M	241	0.08	0.11	96	6.3
6	M	242	0.08	0.12	96	5.8
7	M	244	0.08	0.11	96	5.7
8	M	242	0.08	0.11	95	6.2
9	M	241	0.08	0.11	96	6.6
10	M	243	0.07	0.11	96	5.7
11	M	243	0.08	0.12	95	6.4
12	M	241	0.08	0.11	95	6.1
13	M	242	0.07	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C@ 15 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 3. Accelerated Aging Condition: 60°C @ 22 days      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	244	0.08	0.11	95	6.2
2	M	243	0.08	0.11	96	6.4
3	M	241	0.08	0.11	95	6.0
4	M	244	0.08	0.11	95	6.2
5	M	244	0.07	0.11	96	6.3
6	M	241	0.08	0.11	96	5.8
7	M	242	0.08	0.11	96	5.7
8	M	246	0.08	0.11	95	6.3
9	M	242	0.08	0.11	96	6.6
10	M	243	0.07	0.11	96	5.7
11	M	244	0.08	0.12	95	6.4
12	M	242	0.08	0.11	95	6.1
13	M	244	0.07	0.11	96	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6\text{N}$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 60°C @ 35 days      Conditioning: At least 16 hours****A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 &amp; EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.4
2	M	242	0.08	0.11	96	6.4
3	M	242	0.08	0.12	95	6.3
4	M	242	0.08	0.11	95	6.1
5	M	244	0.08	0.11	95	6.3
6	M	242	0.08	0.11	96	5.8
7	M	243	0.08	0.11	96	5.7
8	M	244	0.08	0.11	95	6.2
9	M	243	0.08	0.11	96	6.6
10	M	242	0.07	0.11	96	5.8
11	M	242	0.08	0.12	95	6.5
12	M	243	0.08	0.11	95	6.1
13	M	245	0.07	0.11	95	6.5
Median Value						6.3

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 &amp; EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 35 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 60°C @ 42 days      Conditioning: At least 16 hours****A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 &amp; EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded

result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.07	0.12	95	6.2
2	M	243	0.08	0.11	96	6.4
3	M	241	0.08	0.11	95	6.0
4	M	242	0.08	0.11	96	6.2
5	M	240	0.08	0.11	96	6.3
6	M	243	0.08	0.11	96	5.8
7	M	242	0.08	0.11	96	5.7
8	M	243	0.08	0.11	95	6.2
9	M	242	0.08	0.11	96	6.5
10	M	241	0.07	0.11	96	5.7
11	M	240	0.08	0.12	95	6.5
12	M	241	0.08	0.11	95	6.1
13	M	243	0.07	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 60°C @ 42 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 6. FINAL RESULTS of LOT NO. 130326072SA07:

Final performance-testing results of samples at conditions of 60°C@ 5 days, 60°C@15 days, 60°C@ 22 days, 60°C@ 35 days, 60°C@ 42 days conform to associate standard requirements, and can be used normally.

### III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C OF LOT NO. 130327072XA07

#### 1. Accelerated Aging Condition: 60°C @ 5 days      Conditioning: At least 16 hours

A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties



Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	244	0.08	0.12	96	6.2
2	M	243	0.08	0.11	96	6.4
3	M	241	0.08	0.11	95	6.2
4	M	243	0.08	0.11	95	6.1
5	M	242	0.08	0.11	96	6.3
6	M	243	0.08	0.11	96	5.8
7	M	241	0.08	0.11	96	5.9
8	M	243	0.08	0.11	95	6.3
9	M	242	0.08	0.11	96	6.6
10	M	241	0.07	0.11	96	5.7
11	M	243	0.08	0.12	95	6.5
12	M	242	0.08	0.11	95	6.1
13	M	242	0.07	0.11	95	6.3
Median Value						6.3

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

## B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

## C. TESTING RESULTS AT 60°C @ 5 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **2. Accelerated Aging Condition: 60°C @ 15 days      Conditioning: At least 16 hours**

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.2
2	M	240	0.08	0.11	96	6.3
3	M	243	0.08	0.11	95	6.0
4	M	242	0.08	0.11	95	6.1
5	M	241	0.08	0.11	96	6.3
6	M	243	0.08	0.11	96	5.8
7	M	241	0.08	0.11	96	5.9
8	M	242	0.08	0.11	95	6.2
9	M	243	0.08	0.11	96	6.6
10	M	242	0.07	0.11	96	5.7
11	M	242	0.08	0.12	95	6.5
12	M	244	0.08	0.11	95	6.1
13	M	241	0.07	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6\text{N}$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 15 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 3. Accelerated Aging Condition: 60°C @ 22 days Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.2

2	M	242	0.08	0.11	96	6.4
3	M	240	0.08	0.11	95	6.0
4	M	241	0.08	0.11	95	6.1
5	M	241	0.07	0.11	96	6.3
6	M	242	0.08	0.11	96	5.7
7	M	241	0.08	0.11	96	5.9
8	M	243	0.08	0.11	95	6.2
9	M	241	0.08	0.11	96	6.5
10	M	242	0.07	0.11	96	5.7
11	M	243	0.08	0.11	95	6.5
12	M	245	0.08	0.11	96	6.1
13	M	243	0.07	0.11	95	6.2
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 60°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 4. Accelerated Aging Condition: 60°C @ 35 days Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.2
2	M	242	0.07	0.12	96	6.3
3	M	240	0.08	0.11	95	6.2
4	M	243	0.08	0.11	95	6.1
5	M	244	0.08	0.11	95	6.4

6	M	242	0.08	0.11	96	5.6
7	M	241	0.08	0.11	96	5.7
8	M	244	0.08	0.11	95	6.1
9	M	243	0.08	0.11	96	6.5
10	M	241	0.07	0.11	96	5.7
11	M	242	0.08	0.12	95	6.4
12	M	242	0.08	0.11	95	6.1
13	M	242	0.07	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 35 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **5. Accelerated Aging Condition: 60°C @ 42 days      Conditioning: At least 16 hours**

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 21°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.07	0.11	96	6.1
2	M	242	0.08	0.11	96	6.3
3	M	240	0.08	0.11	95	6.0
4	M	243	0.08	0.11	95	6.1
5	M	244	0.08	0.11	96	6.3
6	M	242	0.08	0.11	96	5.8
7	M	241	0.08	0.11	96	5.7
8	M	244	0.08	0.11	95	6.2
9	M	243	0.08	0.11	96	6.5

10	M	241	0.07	0.11	96	5.7
11	M	242	0.08	0.12	95	6.4
12	M	242	0.08	0.11	95	6.1
13	M	242	0.07	0.11	95	6.1
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### **B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

#### **C. TESTING RESULTS AT 60°C @ 42 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **6. FINAL RESULTS of LOT NO. 130327072XA07:**

Final performance-testing results of samples at conditions of 60°C@ 5 days, 60°C@ 15 days, 60°C@ 22 days, 60°C @ 35 days, 60°C @ 42 days conform to associate standard requirements, and can be used normally.

#### **IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C:**

Through the accelerated aging performance test at 60°C@ 5 days, 60°C@ 15 days, 60°C @22 days, 60°C @ 35 days, 60°C @ 42 days on 3 lots products(Lot No: 130326061SA06, 130326072SA07, 130327072XA07) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: Xu Lihua/ QA Director of Better Care

Date: May 31, 2013

Reviewed by: Wu Min/ QA Director of Hongray Group

Date: May 31, 2013

# SHIJIAZHUANG HONGRAY GROUP

## PERFORMANCE TESTING REPORT AT 50°C FOR 5 TIME POINT

### **Purpose:**

As per EN455-4, carry out accelerated aging property test at 50°C for 5 time point (namely 22 days, 35 days, 55 days, 90 days, and 110 days) to verify and determine the shelf-life of Powder Free Nitrile Gloves, Blue.

**Date Tested:** June 01-September 20, 2013

### **Samples Tested:**

Gloves manufactured in current production lines of Better Care Plastic Technology Co., Ltd.

Machine No.: No. 6 and 7 Size: M

Product Name: Powder Free Nitrile Gloves, Blue

Product Lot No.: 130326061SA06  
130326072SA07  
130327072XA07

**Standards:** EN 455-4:2009 Medical Gloves for Single Use- Part 4: Requirements and Testing for Shelf life determination

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C OF LOT NO. 130326061SA06**

#### **1. Accelerated Aging Condition: 50°C@ 22 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties  
Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	96	6.5
2	M	240	0.08	0.12	95	6.1
3	M	240	0.08	0.11	95	6.1
4	M	241	0.07	0.11	96	6.0
5	M	240	0.08	0.11	95	6.4



6	M	240	0.08	0.11	96	5.9
7	M	245	0.08	0.11	95	6.1
8	M	244	0.08	0.11	95	6.5
9	M	240	0.08	0.12	95	6.1
10	M	241	0.08	0.11	96	5.9
11	M	241	0.07	0.11	95	6.2
12	M	241	0.08	0.11	95	6.0
13	M	242	0.08	0.11	96	5.9
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **2. Accelerated Aging Condition: 50°C @ 35 days Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	244	0.08	0.12	96	6.6
2	M	240	0.08	0.11	95	6.0
3	M	241	0.08	0.11	95	6.0
4	M	242	0.08	0.11	96	5.9
5	M	241	0.08	0.11	96	6.4
6	M	242	0.07	0.11	95	5.9
7	M	241	0.08	0.11	96	6.5
8	M	243	0.08	0.12	95	6.6
9	M	242	0.07	0.11	96	6.2
10	M	240	0.08	0.11	95	6.2
11	M	242	0.08	0.11	96	5.8

12	M	243	0.08	0.11	95	6.2
13	M	241	0.08	0.11	95	6.3
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 50°C @ 35 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 3. Accelerated Aging Condition: 50°C @ 55 days Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.07	0.11	95	6.3
2	M	241	0.08	0.11	96	5.8
3	M	240	0.08	0.12	95	5.6
4	M	242	0.08	0.11	95	6.2
5	M	241	0.08	0.11	95	6.4
6	M	242	0.08	0.11	96	5.9
7	M	243	0.08	0.11	95	6.2
8	M	244	0.08	0.11	96	6.1
9	M	242	0.08	0.11	96	5.9
10	M	243	0.07	0.12	95	6.0
11	M	241	0.08	0.11	96	5.8
12	M	244	0.08	0.11	95	6.3
13	M	241	0.08	0.11	95	6.5
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong      Zhao Sha      80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 55 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 4. Accelerated Aging Condition: 50°C @ 90 days      Conditioning: At least 16 hours

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen      Test Condition: 22.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.2
2	M	240	0.08	0.12	96	6.0
3	M	242	0.08	0.11	95	6.0
4	M	242	0.07	0.11	95	6.0
5	M	244	0.08	0.11	96	6.3
6	M	242	0.08	0.11	96	5.8
7	M	243	0.08	0.11	96	5.9
8	M	242	0.08	0.11	95	6.0
9	M	240	0.08	0.12	96	6.6
10	M	242	0.08	0.11	95	5.7
11	M	241	0.08	0.11	95	6.5
12	M	242	0.08	0.11	95	6.0
13	M	243	0.08	0.11	95	6.2
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong      Zhao Sha      80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 90 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 50°C @ 110 days      Conditioning: At least 16 hours**

#### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.3
2	M	242	0.08	0.11	96	6.0
3	M	240	0.08	0.11	95	6.4
4	M	242	0.08	0.11	95	6.0
5	M	245	0.07	0.11	96	6.3
6	M	246	0.08	0.11	96	5.7
7	M	244	0.08	0.11	96	5.9
8	M	241	0.08	0.11	95	6.0
9	M	240	0.08	0.11	96	6.4
10	M	244	0.08	0.11	95	5.7
11	M	241	0.07	0.12	95	6.2
12	M	243	0.08	0.11	95	6.0
13	M	243	0.08	0.12	95	6.2
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 110 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 6. FINAL RESULTS of LOT NO. 130326061SA06:

Final performance-testing results of samples at conditions of 50°C@ 22 days, 50°C@ 35 days, 50°C@ 55 days, 50°C@ 90 days, 50°C@ 110 days conform to associate standard requirements, and can be used normally.

## II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C OF LOT NO. 130326072SA07

### 1. Accelerated Aging Condition: 50°C @ 22 days      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	96	6.2
2	M	242	0.08	0.11	96	6.0
3	M	242	0.08	0.11	95	6.6
4	M	241	0.07	0.11	95	6.0
5	M	242	0.08	0.11	96	6.3
6	M	242	0.08	0.11	96	5.8
7	M	243	0.08	0.11	96	5.9
8	M	242	0.08	0.12	95	6.0
9	M	242	0.08	0.11	96	6.4
10	M	244	0.08	0.11	95	5.7
11	M	242	0.08	0.11	95	6.5
12	M	242	0.08	0.11	95	6.3
13	M	241	0.08	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 2. Accelerated Aging Condition: 50°C @ 35 days      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.08	0.12	96	6.2
2	M	242	0.08	0.11	96	6.3
3	M	241	0.08	0.11	95	6.0
4	M	242	0.08	0.11	95	6.4
5	M	244	0.08	0.11	96	6.3
6	M	242	0.08	0.11	96	5.8
7	M	244	0.08	0.11	96	5.9
8	M	245	0.07	0.12	96	6.0
9	M	242	0.08	0.11	96	6.4
10	M	243	0.08	0.11	95	5.7
11	M	243	0.08	0.11	95	6.5
12	M	242	0.08	0.11	95	6.0
13	M	243	0.07	0.11	95	6.5
Median Value						6.3

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C@ 35 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 50°C @ 55 days      Conditioning: At least 16 hours****A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.2
2	M	242	0.08	0.11	96	6.0
3	M	241	0.08	0.11	95	6.0
4	M	242	0.08	0.11	95	6.5
5	M	244	0.08	0.11	95	6.0
6	M	245	0.07	0.12	96	5.8
7	M	242	0.08	0.11	96	5.9
8	M	244	0.08	0.11	95	6.4
9	M	243	0.08	0.11	96	6.6
10	M	241	0.08	0.11	95	5.9
11	M	242	0.08	0.11	95	6.5
12	M	244	0.08	0.11	95	6.4
13	M	243	0.08	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 55 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 50°C @ 90 days      Conditioning: At least 16 hours****A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties**



Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 22.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.5
2	M	241	0.08	0.11	96	6.0
3	M	241	0.08	0.11	95	6.0
4	M	240	0.07	0.12	95	6.0
5	M	243	0.08	0.11	96	6.3
6	M	241	0.08	0.11	96	5.7
7	M	242	0.08	0.11	96	5.9
8	M	242	0.08	0.11	95	6.2
9	M	246	0.08	0.11	96	6.6
10	M	244	0.08	0.11	95	5.7
11	M	243	0.08	0.11	95	6.5
12	M	241	0.08	0.11	95	6.1
13	M	243	0.08	0.11	95	6.2
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

## B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

## C. TESTING RESULTS AT 50°C @ 90 days:

**Final performance-testing results of samples conform to associate standard requirements, and can be used normally.**

## 5. Accelerated Aging Condition: 50°C @ 110 days      Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.12	95	6.2
2	M	240	0.08	0.11	96	6.3
3	M	242	0.08	0.11	95	6.0
4	M	243	0.07	0.11	95	6.1
5	M	241	0.08	0.11	96	6.3
6	M	244	0.08	0.11	96	5.8
7	M	244	0.08	0.11	96	5.7
8	M	242	0.07	0.11	95	6.0
9	M	245	0.08	0.11	96	6.5
10	M	242	0.08	0.11	95	5.7
11	M	243	0.08	0.11	95	6.4
12	M	241	0.08	0.11	95	6.0
13	M	240	0.08	0.11	95	6.2
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### **B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### **C. TESTING RESULTS AT 50°C @ 110 days:**

**Final performance-testing results of samples conform to associate standard requirements, and can be used normally.**

#### **6. FINAL RESULTS of LOT NO. 130326072SA07:**

**Final performance-testing results of samples at conditions of 50°C@ 22 days, 50°C@35 days, 50°C@ 55 days, 50°C@ 90 days, 50°C@ 110 days conform to associate standard requirements, and can be used normally.**

### **III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C OF LOT NO. 130327072XA07**

**1. Accelerated Aging Condition: 50°C @ 22 days Conditioning: At least 16 hours**

#### **A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded

result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21.5°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.11	95	6.2
2	M	240	0.08	0.11	96	6.1
3	M	243	0.08	0.11	95	6.0
4	M	242	0.08	0.11	95	6.6
5	M	245	0.08	0.11	96	6.3
6	M	244	0.07	0.11	96	5.8
7	M	242	0.08	0.12	96	5.9
8	M	240	0.08	0.11	95	6.0
9	M	242	0.08	0.11	96	6.4
10	M	241	0.08	0.11	95	5.7
11	M	245	0.08	0.11	95	6.5
12	M	241	0.08	0.11	96	6.0
13	M	243	0.08	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong

Zhao Sha

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 22 days:

**Final performance-testing results of samples conform to associate standard requirements, and can be used normally.**

## **2. Accelerated Aging Condition: 50°C @ 35 days      Conditioning: At least 16 hours**

### **A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.2
2	M	241	0.08	0.11	96	5.7
3	M	244	0.08	0.11	95	6.0
4	M	242	0.08	0.11	95	6.1
5	M	241	0.08	0.11	96	6.3
6	M	240	0.08	0.11	96	5.8
7	M	242	0.08	0.11	96	5.9
8	M	241	0.08	0.11	95	6.0
9	M	243	0.08	0.11	96	6.2
10	M	244	0.08	0.11	95	5.7
11	M	241	0.08	0.11	95	6.5
12	M	240	0.08	0.12	95	6.0
13	M	242	0.08	0.11	96	6.2
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6\text{N}$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 35 days:

**Final performance-testing results of samples conform to associate standard requirements, and can be used normally.**

### **3. Accelerated Aging Condition: 50°C @ 55 days      Conditioning: At least 16 hours**

#### **A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 21.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		

1	M	242	0.07	0.11	95	6.2
2	M	241	0.08	0.11	96	6.4
3	M	244	0.08	0.11	95	5.9
4	M	242	0.08	0.11	95	6.0
5	M	241	0.08	0.11	96	6.3
6	M	240	0.08	0.11	96	5.8
7	M	242	0.08	0.11	96	5.7
8	M	241	0.08	0.11	95	6.0
9	M	243	0.08	0.11	96	6.3
10	M	244	0.08	0.11	95	5.7
11	M	241	0.08	0.11	95	6.5
12	M	240	0.08	0.11	95	6.2
13	M	242	0.07	0.12	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 50°C @ 55 days:

**Final performance-testing results of samples conform to associate standard requirements, and can be used normally.**

#### 4. Accelerated Aging Condition: 50°C @ 90 days Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen Test Condition: 22.5°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.1
2	M	241	0.08	0.11	96	6.4
3	M	243	0.08	0.11	95	6.0

4	M	242	0.08	0.11	95	6.5
5	M	244	0.08	0.11	96	6.3
6	M	245	0.07	0.12	96	5.8
7	M	242	0.08	0.11	96	5.9
8	M	241	0.08	0.11	96	6.0
9	M	240	0.07	0.11	96	6.6
10	M	242	0.08	0.11	95	5.7
11	M	242	0.08	0.11	95	6.5
12	M	242	0.08	0.11	96	6.3
13	M	243	0.08	0.11	96	6.4
Median Value						6.3

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6\text{N}$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	0

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 90 days:

**Final performance-testing results of samples conform to associate standard requirements, and can be used normally.**

## 5. Accelerated Aging Condition: 50°C @ 110 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Zhao Zhifen

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.11	95	6.2
2	M	242	0.08	0.11	96	6.4
3	M	240	0.08	0.11	95	6.0
4	M	240	0.08	0.11	95	6.1
5	M	243	0.08	0.11	96	6.3
6	M	244	0.08	0.11	96	5.8

7	M	241	0.08	0.11	96	5.9
8	M	240	0.08	0.11	95	6.2
9	M	243	0.08	0.11	96	6.6
10	M	242	0.07	0.11	96	5.7
11	M	244	0.08	0.12	95	6.5
12	M	242	0.08	0.11	95	6.1
13	M	245	0.07	0.11	95	6.2
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### **B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Jia Licong Zhao Sha 80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

#### **C. TESTING RESULTS AT 50°C @ 110 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **6. FINAL RESULTS of LOT NO. 130327072XA07:**

Final performance-testing results of samples at conditions of 50°C@ 22 days, 50°C@ 35 days, 50°C@ 55 days, 50°C @ 90 days, 50°C @ 110 days conform to associate standard requirements, and can be used normally.

#### **IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C:**

Through the accelerated aging performance test at 50°C@ 22 days, 50°C@ 35 days, 50°C @55 days, 50°C @ 90 days, 50°C @ 110 days on 3 lots products(Lot No: 130326061SA06, 130326072SA07, 130327072XA07) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: Xu Lihua/ QA Director of Better Care

Date: Sep 20, 2013

Reviewed by: Wu Min/ QA Director of Hongray Group

Date: Sep 20, 2013



# SHIJIAZHUANG HONGRAY GROUP CO., LTD

## Summary for Accelerated Aging Shelf Life Testing

### 1.0 Purpose:

Conduct accelerated aging shelf life determination for Powder Free Nitrile Gloves, Blue as per EN455-4, so as to determine its shelf life.

### 2.0 Standard:

2.1 EN 455-4:2009: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

2.2 EN 455-1:2000: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

2.3 EN 455-2:2009: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

### 3.0 Samples Information:

Gloves manufactured in current production lines of Better Care Plastic Technology Co., Ltd.

**Machine No.:** No. 6 and 7    Size: M

**Product Name:** Powder Free Nitrile Gloves, Blue

**Product Lot No.:** 130326061SA06

130326072SA07

130327072XA07

### 4.0 Instruction of Sampling Testing:

According to EN455-1 and EN455-2, sample gloves individually from three production lots and conduct the following testing and record the testing data under the condition of time zero and accelerated aging for shelf life determination.

Item		Criteria	Quantity and Acceptance Criteria
Length (mm)		$\geq 240\text{mm}$	13 pieces, median
Width (mm)		$95 \pm 10\text{mm}$	13 pieces, median
Thickness (mm)	Middle Fingertip $t_f$	$t_f/t_x \geq 0.9$	13 pieces
	Test piece $t_x$		
Force at Break (N)		$\geq 6\text{N}$	13 pieces, median
Watertightness		---	G-I, AQL1.5, sampling 80 pieces (Ac3, Re 4)
Notes:			
1. Condition of sampling testing: Temperature: $23 \pm 2^\circ\text{C}$ , Humidity: $50 \pm 5\%$			
2. Samples shall be conditioned at least 16 hours before testing.			

If all the testing results comply with the criteria requirements, and if the rate of change for the force at break tested exceed threshold value of 75% retained force at break, then the lot of products will be accepted. On the contrary, it will be rejected.

### 5.0 Summary for Accelerated Aging Shelf Life Determination Study:

### 5.1 Time Zero Testing:

5.1.1 Time zero testing for Nitrile gloves were conducted from March 27, 2013. Based on the performance test results, it is showed that the samples meet associate standard requirements, and can be used normally and accelerated aging shelf life determination study.

### 5.2 Accelerated Aging Shelf Life Testing:

5.2.1 As per Annex B in EN 455-4, 4 different temperatures and 5 time point at each temperature are used for accelerated aging shelf life testing, and the testing is continued at least 180 days. The selected temperature and days are as follows:

# \ Temp	80°C	70°C	60°C	50°C
1	1 Day	1 Day	5 Days	22 Days
2	2 Days	3 Days	15 Days	35 Days
3	3 Days	7 Days	22 Days	55 Days
4	4 Days	8 Days	35 Days	90 Days
5	5 Days	10 Days	42 Days	110 Days

5.2.2 As per the arrangements in the above table, the actual schedule for each testing are as follows:

Temp \ Testing Period	80°C	70°C	60°C	50°C
	2013.03.27-04.02	2013.04.03-04.14	2013.04.15-05.30	2013.06.01-09.20

5.2.3 The accelerated aging testing was performed as per the above condition and schedule, and based on the accelerated aging performance testing results and also the rate of change for the force at break tested, it is showed that the samples meet associated standard requirements.

Details for accelerated aging testing for each condition refer to corresponding testing report.

### 5.3 Conclusion for accelerated aging performance testing:

Through the time zero and accelerated aging performance test according to the condition listed in section 5.1 and 5.2 on 3 lots products (namely Lot No: 130326061SA06, 130326072SA07, 130327072XA07 as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and the maximum shelf life of Powder Free Nitrile Gloves, Blue determined by accelerated aging testing is 3 years.

Prepared by:  Xu Lihua/ QA Director of Better Care

Date: Sep 30, 2013

Reviewed by:  Wu Min/ QA Director of Hongray Group

Date: Sep 30, 2013

## SHIJIAZHUANG HONGRAY GROUP

South Tongda Rd., East Dist. Jinzhou City  
Hebei , 052260, China  
TEL: 86-311-66179668  
FAX: 86-311-66179676  
www.hongray.com

### SPECIFICATION FOR NITRILE EXAMINATION GLOVE

**1.0 Product:** Nitrile, Powder Free, Fingertip-textured/Full textured, 9" length, for examination use

**2.0 Dimensions:**

Size	Median Length (mm)	Median Width (mm)	Thickness (mm)(min)	
			Palm	Finger
XS	240	$70 \pm 10$	0.07	0.08
S	240	$80 \pm 10$	0.07	0.08
M	240	$95 \pm 10$	0.07	0.08
L	240	$110 \pm 10$	0.07	0.08
XL	240	$120 \pm 10$	0.07	0.08

**3.0 Strength:**

Force at break: 6N (Median)

**4.0 Water Leakage Testing:**

According to ISO2859, G-I, Single Sampling Plan, AQL1.5

**5.0 Powder Residues:**

For powder free gloves, not more than 2mg per glove.



中华人民共和国  
PEOPLE'S REPUBLIC OF CHINA  
医疗器械产品出口销售证明  
CERTIFICATE FOR EXPORTATION OF MEDICAL  
PRODUCTS

证书编号：冀石药监械出 20200017

Certificate NO.: Certificate of medical device exports made in shijiazhuang  
issued by Hebei Drug Supervision Administration No. 20200017

产品名称：详见附表

Product(s): Details as per attached list.

规格型号：详见附表

Model: Details as per attached list.

产品注册或备案凭证号：详见附表

Registration certificate(s): Details as per attached list.

生产企业：石家庄鸿锐集团有限公司

Manufacturer: Shijiazhuang Hongray Group Co., Ltd

生产企业住所：河北省晋州市通达路东段路南；河北省赞皇县东高工业园区；河北省  
深泽县工业园区（府前西路）

Address of manufacturer: South Tongda Rd., East Dist. Jinzhou City, CHINA  
052260; Donggao Industrial Zone Zanhuang, Hebei, China 050000; Fuqian Xi  
Road, West district of Shenze Industrial Base, Shenze County, Hebei  
Province, CHINA 050000

生产许可或备案凭证号：冀石食药监械生产备 20150008 号

Manufacturing License(s): medical device on file under Shijiazhuang Food  
and Drug Supervision Administration, Hebei Province No. 20150008

兹证明上述产品已准许在中国生产和销售。 This is to certify that the  
above products have been registered to be manufactured and sold in  
China.

证明有效期至： 2022 年 03 月 16 日

This certification valid until: Mar.16,2022

备注：

Remark:

2020 年 03 月 17 日



附表

序号	产品名称 中文 /Chinese	产品名称英文 /English	规格型号 中文 /Chinese	规格型号 英文 /English	注册证号 中文 /Chinese	注册证号英文 /English
2	一次性使用 医用 PVC 手套	disposable vinyl examination gloves	本产品分非 消毒和经环 氧乙烷消毒 型两种。非 消毒型分为： XS、S、M 、L、XL 100 只/盒 10 盒/箱、 50 只/盒 10 盒/箱、2 只 /袋 50 袋/ 小箱 10 小 箱/大箱； 消毒型分： XS、S、M 、L、XL 2 只/袋 50 袋/小箱 10 小箱/大箱、 2 只/袋 100 袋/小箱 10 小箱/大箱、 2 只/袋 125 袋/小箱 4 小箱/大箱、 1 只/袋 200 袋/小箱 10 小箱/大箱、 1 只/袋 100 袋/小箱 10 小箱/大箱。 按表面型式 分为两种， 有粉表面和 无粉表面。 有粉手套的	This product includes two types: Non- sterile and Sterilize by ETO. Non- sterile products include 5 Sizes: XS, S, M, L and XL; 100pcs/bo x and 10boxes/c ase; 50pcs/box and 10boxes/c ase; 2pcs/bag, 50bags/ca se and 10cases/m aster case. Sterile products include 5 Sizes: XS, S, M, L and XL; 2pcs/bag,	冀石械备 20150025 号	Registration of Medical Devices filed by Shijiazhuang Food and Drug Supervision Administration No.20150025

			<p>表面处理剂是玉米淀粉。按长度不同分为 9" 和 12" 两种。</p>	<p>50bags/case and 10cases/master case; 2pcs/bag, 100bags/case and 10cases/master case; 2pcs/bag, 125bags/case and 4cases/master case; 1pcs/bag, 200bags/case and 10cases/master case; According to the surface process method, there are two types of gloves (Powder Free and Pre-powdered ). The surface treatment agent for Pre-powdered gloves is corn starch. There are two types of gloves which 9" and 12" by length.</p>	
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1	一次性使用 医用丁腈手 套	disposable nitrile examination gloves	<p>本产品分非 消毒和经环 氧乙烷消毒 型两种。非 消毒型分为： XS、S、M 、L、XL 100 只/盒 10 盒/箱、 50 只/盒 10 盒/箱、2 只 /袋 50 袋/ 小箱 10 小 箱/大箱； 消毒型分： XS、S、M 、L、XL 2 只/袋 50 袋/小箱 10 小箱/大箱、 2 只/袋 100 袋/小箱 10 小箱/大箱、 2 只/袋 125 袋/小箱 4 小箱/大箱、 1 只/袋 200 袋/小箱 10 小箱/大箱、 1 只/袋 100 袋/小箱 10 小箱/大箱。 按表面型式 分为两种， 有粉表面和 无粉表面。 有粉手套的 表面处理剂 是玉米淀粉。 按长度不同 分为 9" 和 12" 两种。</p>	<p><b>This product includes two types:</b> <b>Non- sterile and Sterilize by ETO.</b> <b>Non- sterile products include 5 Sizes: XS, S, M, L and XL; 100pcs/bo x and 10boxes/c ase; 50pcs/box and 10boxes/c ase; 2pcs/bag, 50bags/ca se and 10cases/m aster case.</b> <b>Sterile products include 5 Sizes: XS, S, M, L and XL; 2pcs/bag, 50bags/ca se and 10cases/m aster case; 2pcs/bag, 100bags/c ase and 10cases/m aster case; 2pcs/bag, 125bags/c</b></p>	冀石械备 20150026 号	<p><b>Registration of Medical Devices filed by Shijiazhuang Food and Drug Supervision Administration No.20150026</b></p>
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				<p>ase and 4cases/ma ster case; 1pcs/bag, 200bags/c ase and 10cases/m aster case; Accordin g to the surface process method, there are two types of gloves (Powder Free and Pre- powdered ). The surface treatment agent for Pre- powdered gloves is corn starch. There are two types of gloves which 9" and 12" by length.</p>		
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# POWDER CONTENT TESTING RECORD

Document No.	BA-R-015	Revision Date	2013.08.01	Revision Times	2	Issued Date	2002.12.1
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Product Name: Nitrile Pre-powdered ☐ Powder Free ☒ Color: blue  
Textured ☒ Smooth ☐ Others: ✓

Customer Name/Production Line: SETINO PO No./ Lot Number: 01-G-3

Testing Date: 2020.5.24 Testing Time: 10:00

Testing Equipment #: Incubator: H23C-013-002 Electronic balance: H23C-015-001

Test Record: Take the average result of five gloves,  
Unit: For pre-powdered glove, the result for powder content should be conversed to mg/dm<sup>2</sup>.  
For Powder free glove, the unit for powder content is mg/glove.

Size:	<u>M</u>	<u>L</u>				
Average content per glove	<u>0.54mg</u>	<u>0.84mg</u>				
Average content per dm <sup>2</sup>	<u>✓</u>	<u>✓</u>				

Powder Content Criteria: Not more than 10mg/dm<sup>2</sup> for pre-powdered glove.

Not more than 2mg/glove for powder free glove.

Test Result:



Fail ☐

QA Director: Xu Li Hua

Inspector: DI Na



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### Establishment:

BETTER CARE PLASTIC TECHNOLOGY CO., LTD.

Fuqian Xi Road,

West District Of Shenze Industrial Base

Shenze County, Hebei Province Hebei, CN 050000

**Registration Number:** 3007842585

**FEI Number\*:** 3007842585

**Status:** Active

**Date Of Registration Status:** 2020

### Owner/Operator:

[Better Care Plastic Technology Co., Ltd](#)<sup>6</sup>

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Shenze, Hebei CN 050000

**Owner/Operator Number:** [10030163](#)<sup>7</sup>

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\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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U.S. Department of **Health & Human Services**

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# Medizinprodukte - Informationssystem

- Übersicht
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- Klinische Prüfungen ▾
- Adresse ▾
- Firmenfusion ▾
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## PRODUKT

Produkttyp	nichtaktives Medizinprodukt
Klasse	I
App (Software auf mobilen Endgeräten)	Nein
Tragen alle Medizinprodukte eine CE-Kennzeichnung und werden innerhalb ihrer Zweckbestimmung eingesetzt?	—

## Medizinprodukt

Handelsname	—
Allgemeine Produktbezeichnung	Disposable Nitrile Examination Glove
Nomenklaturcode	11-882
Nomenklaturbezeichnung	Handschuh, Untersuchung/Behandlung
Kategorie	Produkte zum Einmalgebrauch
Kurzbeschreibung in Deutsch	Der Handschuh ist ein nicht steriles Einweggerät für medizinische Zwecke, das an der Hand des Untersuchers getragen wird, um eine Kontamination zwischen Patient und Prüfer zu verhindern. Größen: XS, S, M, L, XL, XXL.
Kurzbeschreibung in Englisch	The glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Sizes: XS, S, M, L, XL, XXL.

## 1. Hersteller

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Postleitzahl	052260
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September 19, 2018

• **TEST REPORT** •

PN 143533

**CHEMICAL ANALYTICAL SERVICES**

Prepared For:

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September 19, 2018

Renmin  
**Better Care Plastic Technology Co., Ltd.**

Page 1 of 6 – PN 143533

**SUBJECT:** Permeation testing per ASTM D6978 on one glove sample submitted by the above company.

**RECEIVED:** Sixty (60) blue gloves identified as; Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

**TEST CHEMICALS:**

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot # 018M4057V; Exp. 04/2019
Cisplatin, 1 mg/ml (1,000 ppm)	WG Critical Care; Lot# 7LO4842; Expiration 04/2019
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Sandoz Inc.; Lot# 17101325; Expiration 10/12/2019
Dacarbazine (DTIC), 10 mg/ml (10,000 ppm)	Teva; Lot# 31322092B; Expiration 11/2019
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	Actavis Pharma; Lot# 7LJ5121; Expiration 07/2019
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Accord; Lot# X02633; Expiration 01/2020
Fluorouracil, 50 mg/ml (50,000 ppm)	Sigma Aldrich; Lot# MKCD1558; Expiration 09/2019
Methotrexate, 25 mg/ml (25,000 ppm)	Hospira; Lot# E124437AA; Expiration 07/2019
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	Hospira; Lot# E036865AA; Expiration 09/2018
Thiotepa (THT), 10 mg/ml (10,000 ppm)	USP; Lot # R046R0; Exp. 05/2019
Bleomycin, 15.0 mg/ml (15,000 ppm)	USP; Lot# L1L527; Expiration 12/2018
Busulfan, 6.0 mg/ml (6,000 ppm)	Sigma; CAS# 55-98-1; Lot# BCBS8240V
Carboplatin, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 171110A; Expiration 09/2019
Chloroquine, 50.0 mg/ml (50,000 ppm)	USP; Lot# F1L501; Expiration 08/2019
Cyclosporin A, 100.0 mg/ml (100,000 ppm)	USP; Lot# J0M382; Expiration 08/2019
Cytarabine, 100.0 mg/ml (100,000 ppm)	USP; Lot# R046F0; Expiration 04/2019
Daunorubicin, 5.0 mg/ml (5,000 ppm)	Sigma Aldrich; Lot# 125M4750V; Expiration 03/2019
Docetaxel, 10.0 mg/ml (10,000 ppm)	LC Labs; Lot# BDC-117; Expiration 01/2025
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	LC Labs; Lot# EPR-101; Expiration 12/2018
Fludarabine, 25.0 mg/ml (25,000 ppm)	USP; Lot# H1K220; Expiration 12/2019
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	LC Labs; Lot# GMC-105; Expiration 1/6/2025
Idarubicin, 1.0 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# R080E0; Expiration 12/2019
Ifosfamide, 50.0 mg/ml (50,000 ppm)	West-Ward; Lot# BH0007; Expiration 11/2018
Irinotecan, 20.0 mg/ml (20,000 ppm)	LC Labs; Lot# RCN-105; Expiration 03/2024
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	Sigma Aldrich; Lot# MKBW4481V; Expiration 03/2019
Melphalan, 5 mg/ml (5,000 ppm)	Sigma Aldrich; Lot# 072M4056V; Expiration 12/2018
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# MKBT1043V; Expiration 02/2019
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 02/2019
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	LC Labs; Lot# XAP-111; 12/2019
Paraplatin, 10 mg/ml (10,000 ppm)	Teva; Lot# 171110A; Expiration 09/2019
Retrovir, 10 mg/ml (10,000 ppm)	USP; Lot# R052L0; Expiration 12/2018
Rituximab, 10 mg/ml (10,000 ppm)	Hetero Oncology; Lot# RB1710A; Expiration 12/2019
Topotecan HCl, 1 mg/ml (1,000 ppm)	USP; Lot# R007C0; Expiration 12/2018
Trisenox, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# BCBQ8570V; Expiration 12/2018
Velcade (Bortezomib), 1 mg/ml (1,000 ppm)	LC Labs; Lot# BBZ-116; Expiration 4/2025
Vincristine, 1.0 mg/ml (1,000 mg/ml)	Hospira; Lot# E047139AAI Expiration 04/2019



**COLLECTION MEDIA:**

Table 2. Collection Media for Test Chemicals

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa (THT), 10 mg/ml (10,000 ppm)	Distilled Water
Bleomycin, 15.0 mg/ml (15,000 ppm)	Distilled Water
Busulfan, 6.0 mg/ml (6,000 ppm)	Distilled Water
Carboplatin, 10.0 mg/ml (10,000 ppm)	Distilled Water
Chloroquine, 50.0 mg/ml (50,000 ppm)	Distilled Water
Cyclosporin, 100.0 mg/ml (100,000 ppm)	Distilled Water
Cytarabine, 100.0 mg/ml (100,000 ppm)	Distilled Water
Daunorubicin, 5.0 mg/ml (5,000 ppm)	Distilled Water
Docetaxel, 10.0 mg/ml (10,000 ppm)	Distilled Water
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	Distilled Water
Fludarabine, 25.0 mg/ml (25,000 ppm)	Distilled Water
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	Distilled Water
Idarubicin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Irinotecan, 20.0 mg/ml (20,000 ppm)	Distilled Water
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	Distilled Water
Melphalan, 5 mg/ml (5,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	Distilled Water
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	Distilled Water
Paraplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Retrovir, 10 mg/ml (10,000 ppm)	Distilled Water
Rituximab, 10 mg/ml (10,000 ppm)	Distilled Water
Topotecan HCl, 1 mg/ml (1,000 ppm)	Distilled Water
Trisenox, 1 mg/ml (1,000 ppm)	Distilled Water
Velcade (Bortezomib), 1 mg/ml (1,000 ppm)	Distilled Water
Vincristine, 1.0 mg/ml (1,000 mg/ml)	Distilled Water

**TESTING CONDITIONS:**

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm <sup>2</sup>
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area



**DETECTION METHOD OF CHEMICAL PERMEATION:**

**UV/VIS ABSORPTION SPECTROMETRY:**

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	200
Dacarbazine (DTIC), 10 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	205
Fluorouracil, 50 mg/ml (50,000 ppm)	269
Methotrexate, 25 mg/ml (25,000 ppm)	303
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	231
Thiotepa (THT), 10 mg/ml (10,000 ppm)	199
Bleomycin, 15.0 mg/ml (15,000 ppm)	290
Busulfan, 6.0 mg/ml (6,000 ppm)	197
Carboplatin, 10.0 mg/ml (10,000 ppm)	192
Chloroquine, 50.0 mg/ml (50,000 ppm)	220
Cyclosporin, 100.0 mg/ml (100,000 ppm)	199
Cytarabine, 100.0 mg/ml (100,000 ppm)	272
Daunorubicin, 5.0 mg/ml (5,000 ppm)	269
Docetaxel, 10.0 mg/ml (10,000 ppm)	231
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	233 & 253
Fludarabine, 25.0 mg/ml (25,000 ppm)	261
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	202
Idarubicin, 1.0 mg/ml (1,000 ppm)	257
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Irinotecan, 20.0 mg/ml (20,000 ppm)	200
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	194
Melphalan, 5 mg/ml (5,000 ppm)	260
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	242
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	199
Paraplatin, 10 mg/ml (10,000 ppm)	192
Retrovir, 10 mg/ml (10,000 ppm)	266
Rituximab, 10 mg/ml (10,000 ppm)	192
Topotecan HCl, 1 mg/ml (1,000 ppm)	254
Trisenox, 1 mg/ml (1,000 ppm)	197
Velcade (Bortezomib), 1 mg/ml (1,000 ppm)	206
Vincristine, 1.0 mg/ml (1,000 mg/ml)	220

**SAMPLE CHARACTERISTICS:**

Table 4. Cuff thickness characteristics for the tested: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

Testing Drug	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m <sup>2</sup> )
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.054	0.053	0.053	0.054	51.0
Cisplatin	0.052	0.051	0.053	0.052	
Cyclophosphamide	0.051	0.053	0.054	0.053	
Dacarbazine (DTIC)	0.053	0.052	0.056	0.054	
Doxorubicin Hydrochloride	0.051	0.052	0.057	0.053	
Etoposide (Toposar)	0.051	0.053	0.055	0.053	
Fluorouracil	0.057	0.056	0.055	0.056	
Methotrexate	0.052	0.056	0.051	0.053	
Paclitaxel (Taxol)	0.051	0.057	0.053	0.054	
Thiotepa (THT)	0.050	0.055	0.051	0.052	
Bleomycin	0.048	0.047	0.045	0.047	48.9
Busulfan	0.052	0.044	0.046	0.047	
Carboplatin	0.047	0.047	0.045	0.046	
Chloroquine	0.048	0.047	0.045	0.047	
Cyclosporin	0.047	0.044	0.045	0.045	
Cytarabine	0.048	0.048	0.047	0.047	
Daunorubicin	0.046	0.046	0.044	0.046	
Docetaxel	0.045	0.045	0.045	0.045	
Epirubicin (Ellence)	0.045	0.046	0.046	0.045	
Fludarabine	0.048	0.045	0.046	0.046	
Gemcitabine (Gemzar)	0.047	0.047	0.047	0.047	
Idarubicin	0.047	0.046	0.045	0.046	
Ifosfamide	0.046	0.047	0.047	0.047	
Irinotecan	0.047	0.046	0.045	0.046	
Mechlorethamine HCl	0.046	0.046	0.044	0.045	
Melphalan	0.049	0.047	0.047	0.048	
Mitomycin C	0.048	0.046	0.047	0.047	
Mitoxantrone	0.048	0.046	0.045	0.046	
Oxaliplatin	0.045	0.044	0.045	0.045	
Paraplatin	0.043	0.043	0.045	0.043	
Retrovir	0.045	0.045	0.049	0.046	
Rituximab	0.046	0.045	0.047	0.046	
Topotecan HCl	0.043	0.047	0.045	0.045	
Trisenox	0.045	0.048	0.045	0.046	
Velcade (Bortezomib)	0.045	0.044	0.046	0.045	
Vincristine	0.045	0.044	0.044	0.044	



**RESULTS:**

Table 5. Permeation Test Results on Testing of: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ( $\mu\text{g}/\text{cm}^2/\text{minute}$ )	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	11.0 (14.4, 11.4, 11.0)	0.4 (0.4, 0.4, 0.3)	Moderate swelling and slight degradation
Cisplatin, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Fluorouracil, 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240	N/A	Slight Swelling and no degradation
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Thiotepa (THT), 10 mg/ml (10,000 ppm)	28.8 (38.6, 28.8, 32.7)	1.6 (1.6, 1.4, 1.9)	Slight swelling and no degradation
Bleomycin, 15.0 mg/ml (15,000 ppm)	>240	N/A	Slight swelling and no degradation
Busulfan, 6.0 mg/ml (6,000 ppm)	>240	N/A	Slight swelling and no degradation
Carboplatin, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Chloroquine, 50.0 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Cyclosporin, 100.0 mg/ml (100,000 ppm)	>240	N/A	Slight swelling and no degradation
Cytarabine, 100.0 mg/ml (100,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Daunorubicin, 5.0 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Docetaxel, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Fludarabine, 25.0 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation

**RESULTS cont.:**

Table 5. Permeation Test Results on Testing of: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ( $\mu\text{g}/\text{cm}^2/\text{minute}$ )	OTHER OBSERVATIONS
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	>240	N/A	Slight swelling and no degradation
Idarubicin, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	>240	N/A	Slight Swelling and no degradation
Irinotecan, 20.0 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	>240	N/A	Slight swelling and no degradation
Melphalan, 5.0 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Paraplatin, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Retrovir, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Rituximab, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Topotecan HCl, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Trisenox, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Velcade (Bortezomib), 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Vincristine, 1.0 mg/ml (1,000 mg/ml)	>240	N/A	Slight swelling and no degradation



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Ana C. Barbur, M.S.,  
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Analytical & Chemical Services

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Auditee :	<b>Ever Light Plastic Products Co., Ltd.</b>
Audit Date From :	<b>15/10/2020</b>
Audit Date To :	<b>16/10/2020</b>
Expiry Date of the Audit :	<b>Please refer to the producer profile in the amfori BSCI platform</b>
Auditing Company :	<b>BureauVeritas</b>
Auditor's Name(s) :	<b>Ferric He(Lead), Vera Wang</b>
Auditing Branch (if applicable) :	

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## Rating Definitions



Rating	A combination of ratings per Performance Area where:	Consequence																																							
<b>A</b> <b>Very Good</b>	<ul style="list-style-type: none"><li>• Minimum 7 Performance Areas rated A</li><li>• No Performance Areas rated C, D or E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr></table>	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	B	A	A	A	A	A	A	A	B	B	B	B	B	B	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	A	A	A	A	A	A	A																													
A	A	A	A	A	A	A	A	A	A	B	B	B																													
A	A	A	A	A	A	A	B	B	B	B	B	B																													
<b>B</b> <b>Good</b>	<ul style="list-style-type: none"><li>• Maximum 3 Performance Areas rated C</li><li>• No Performance Areas rated D or E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td></tr><tr><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td></tr></table>	A	A	A	A	A	A	B	B	B	B	B	B	B	A	A	A	A	A	B	B	B	B	B	B	B	C	B	B	B	B	B	B	B	B	B	B	C	C	C	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	B	B	B	B	B	B	B																													
A	A	A	A	A	B	B	B	B	B	B	B	C																													
B	B	B	B	B	B	B	B	B	B	C	C	C																													
<b>C</b> <b>Acceptable</b>	<ul style="list-style-type: none"><li>• Maximum 2 Performance Areas rated D</li><li>• No Performance Areas rated E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>C</td><td>C</td><td>C</td><td>C</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td></tr><tr><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td></tr></table>	A	A	A	A	A	A	A	A	A	C	C	C	C	A	A	A	A	A	B	B	B	B	C	C	C	D	C	C	C	C	C	C	C	C	C	C	C	D	D	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	C	C	C	C																													
A	A	A	A	A	B	B	B	B	C	C	C	D																													
C	C	C	C	C	C	C	C	C	C	C	D	D																													
<b>D</b> <b>Insufficient</b>	<ul style="list-style-type: none"><li>• Maximum 6 Performance Areas rated E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>D</td><td>D</td><td>D</td></tr><tr><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td><td>D</td><td>E</td></tr><tr><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	A	A	A	A	D	D	D	A	A	A	B	B	B	C	C	C	D	D	D	E	D	D	D	D	D	D	D	D	E	E	E	E	E	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	A	D	D	D																													
A	A	A	B	B	B	C	C	C	D	D	D	E																													
D	D	D	D	D	D	D	D	E	E	E	E	E																													
<b>E</b> <b>Unacceptable</b>	<ul style="list-style-type: none"><li>• Minimum 7 Performance Areas rated E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>A</td><td>A</td><td>B</td><td>B</td><td>C</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	E	E	E	E	E	E	E	A	A	B	B	C	D	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	amfori BSCI Participants shall closely oversee the auditee's progress as the producer may represent a higher risk than other business partners.
A	A	A	A	A	A	E	E	E	E	E	E	E																													
A	A	B	B	C	D	E	E	E	E	E	E	E																													
E	E	E	E	E	E	E	E	E	E	E	E	E																													
<b>Zero Tolerance</b>	A Zero Tolerance Issue was identified (see amfori BSCI System Manual Part V – Annex 5: amfori BSCI Zero Tolerance Protocol)	Immediate actions are required. The amfori BSCI Zero Tolerance Protocol is to be followed.																																							

**Main Auditee Information**

Name of producer :	Ever Light Plastic Products Co., Ltd.		
DBID number :	404417		
Audit ID :	195058		
Address :	Donggao Industrial Zone, Zanhuan Shijiazhuang		
Province :	Hebei	Country :	China
Management Representative :	Min Ren		
Contact person:	Min Ren	Sector :	Non-Food
Industry Type :	Plastic Industry	Product group :	Plastic and articles thereof
Product Type :	PVC gloves		



**Audit Details**


Audit Range :	<input checked="" type="checkbox"/> Full Audit	<input type="checkbox"/> Follow-up Audit
Audit Scope :	<input checked="" type="checkbox"/> Main Auditee	<input type="checkbox"/> Main Auditee & Farms
Audit Environment :	<input checked="" type="checkbox"/> Industrial	<input type="checkbox"/> Agricultural <input type="checkbox"/> Small Producer
Audit Announcement :	<input checked="" type="checkbox"/> Fully-Announced	<input type="checkbox"/> Fully-Unannounced <input type="checkbox"/> Semi-Announced
Random Unannounced Check (RUC) :	No	
Audit extent (if applicable) :	none	
Audit interferences or contingencies (if applicable) :	none	
Overall rating :	C	
Need of follow-up :	Yes	If YES, by : 16/10/2021

**Rating per Performance Area (PA)**

PA 1	PA 2	PA 3	PA 4	PA 5	PA 6	PA 7	PA 8	PA 9	PA 10	PA 11	PA 12	PA 13
B	B	A	A	B	D	A	A	A	A	A	A	A

**Executive summary of audit report**

Factory name: Ever Light Plastic Products Co., Ltd. 石家庄鸿锐集团鸿迪塑胶制品有限公司  
 Factory address: Donggao Industrial Zone, Zanhuan, Hebei Province, China.  
 中国河北省赞皇县东高工业区  
 Business license number: 91130100784064765D

The factory was established on January 18, 2006, it was mainly manufacturing PVC gloves. The main production activities in the factory were mixing, molding, testing, inspection and packing.  
 Per factory management interview, there was no peak season in the factory. Their capacity was 80,000 boxes per month.  
 The audited factory owned one 1-storey production building (partial area was 2-storey), one 1-storey canteen and one 3-storey dormitory building. No transportation was provided for workers.  
 There were totally 163 employees in the factory, including 34 non-production employees and 129 production employees. There were 46 male employees and 117 female employees. The youngest employee worked in the factory was 26 years old.  
 Production workers' working hours were recorded by IC card system with detailed time in and time out information. There was only three shifts for production employees, the 1st shift was from 08:00 to 16:00, the 2nd shift was from 16:00 to 24:00 and the 3rd shift was from 00:00 to 08:00; there was one shift for office workers, it was from 08:00 to 12:00 and 13:30 to 17:30, no overtime work arranged in weekdays. Production workers were paid in daily rate at the 25th day of next month by cash.

According to the payroll and attendance records of 16 sample employees from Nov 2019, 16 sample employees from Feb 2020 and 16 sample employees from Aug 2020, it was noted that the regular wage of all sampled employees in these months was minimum RMB 90 per day, the local minimum wage was RMB 1680 per month equivalent to RMB 77/day since Nov 1, 2019 and the local minimum RMB 1480/month and equivalent to RMB 68/day before Nov 1, 2019. All sampled employees were paid with 200% of regular wages for their work on rest days, which was in line with statutory requirement. No overtime works were noted in weekdays and statutory holidays. Additional 5 records were sampled in Sep 2020 for working hour verification. The sampled records indicated that employees' maximum overtime hours was 0 hours a weekday, 8 hours a rest day, 0 hour a holiday, 8 hours a week and 40 hours a month in the testing months. The maximum weekly working hours were 48 hours. The longest consecutive working days were 6 days in the testing periods.

According to the social insurance payment receipt of Sep 2020 provided by factory management, it was noted that only 46 out of 163 employees (28.22%) were provided with pension, unemployment, maternity and medical insurance, all 163 workers were provided with accident insurance, but not all workers were provided with all kinds of social insurance.

The attendance records were cross-checked against production records, attendance records, payroll records and confidential interviews, no inconsistencies regarding working hours were found.  
 At the end of the audit, a closing meeting was held with the factory representatives. All of the findings were disclosed and discussed and a corrective action plan was explained to the factory representatives, Mrs. Min Ren/QA supervisor agreed with the findings and signed the corrective action plan.

Opening meeting factory representatives (name and titles)  
 Mrs. Caihui Wang/HR staff;  
 Mr. Lijie Tian/Sales supervisor;  
 Mrs. Lili Zhang/Quality supervisor;  
 Mr. Nan Zou/Health and safety supervisor;  
 Mrs. Yuli Wu/Manager;  
 Mr. Dongbo Qi/Worker representative;  
 Mrs. Min Ren/QA supervisor;

**Remark:**

- There was no contractor used by the auditee, which makes the contractor license/permit not applicable.
- There was no agency used by the auditee, which makes the agency labor contract not applicable.
- The Government waivers were not applicable in the auditee.
- The Collective bargaining agreements were not applicable in the auditee.

5. Audit Company: Bureau Veritas Consumer Products Service  
Audit Company APSCA Number: 11600002  
Lead Auditor Name: Ferric He  
APSCA Auditor Registered Number: RA 21702093  
Member Auditor Name: Vera Wang  
APSCA Auditor Registered Number: RA 21700004

**Ratings Summary**


Auditee's background information			
Auditee's name :	<b>Ever Light Plastic Products Co., Ltd.</b>	Legal status :	<b>Limited company</b>
Local Name :	石家庄鸿锐集团鸿迪塑胶制品有限公司 (91130100784064765D)	Year in which the auditee was founded :	<b>2006</b>
Address :	<b>Donggao Industrial Zone, Zanzhuang</b>	Contact person (please select) :	<b>Min Ren</b>
Province :	<b>Hebei</b>	Contact's Email :	<b>renmin@hongray.com.cn</b>
City :	<b>Shijiazhuang</b>	Auditee's official language(s) for written communications :	<b>Chinese</b>
Region :	<b>North East Asia</b>	Other relevant languages for the auditee :	<b>None</b>
Country :	<b>China</b>	Website of auditee (if applicable) :	<b>None</b>
GPS coordinates :	<b>N37°42'20" E114°30'9"</b>	Total turnover (in Euros) :	<b>12671059.00</b>
Sector :	<b>Non-Food</b>	Of which exports % :	<b>80.00</b>
Industry :	<b>Plastic Industry</b>	Of which domestic market % :	<b>20.00</b>
If other, please specify :		Production volume :	<b>80,000 boxes per month</b>
Product Group :	<b>Plastic and articles thereof</b>	Production cost calculation :	<b>Yes</b>
If other, please specify :		Lost time injury calculation cost :	<b>Yes</b>
Product Type :	<b>PVC gloves</b>		

Auditee's employment structure at the time of the audit		
Total number of workers :	<b>163</b>	Total number of workers in the production unit to be monitored (if applicable) :
		<b>0</b>
	MALE WORKERS	FEMALE WORKERS
Permanent workers	<b>46</b>	<b>117</b>
Temporary workers	<b>0</b>	<b>0</b>
In management positions	<b>0</b>	<b>1</b>
Apprentices	<b>0</b>	<b>0</b>
On probation	<b>0</b>	<b>0</b>
With disabilities	<b>0</b>	<b>0</b>
Migrants (national citizens)	<b>0</b>	<b>0</b>
Migrants (foreign citizens)	<b>0</b>	<b>0</b>
Workers on the permanent payroll	<b>46</b>	<b>117</b>
Production based workers	<b>0</b>	<b>0</b>
With shifts at night	<b>20</b>	<b>109</b>
Unionised	<b>0</b>	<b>0</b>
Pregnant	<b>-</b>	<b>0</b>
On maternity leave	<b>-</b>	<b>0</b>

## Finding Report



### Performance Area 1 : Social Management System and Cascade Effect

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: B

Deadline date: 16/12/2020

#### GOOD PRACTICES:

None

#### AREAS OF IMPROVEMENT:

The factory established complete policy and procedure on social accountability. For example, the procedures on hiring, discrimination, forced labor, freedom of association, payment and benefit, working hours, dealing with grievances, training workers, promoting ethical behavior were established by the factory. The factory also established policy to manage its own significant business partners, supplier's social performance were monitored when they select suppliers. However, there were gaps had been identified in this performance area.

工厂建立了完整的社会责任政策和程序，例如程序中包括招聘、歧视、强迫劳动、自由结社、工资报酬、工作时间、申诉系统、员工培训、反腐败等内容。工厂还创建了供应商的筛选程序，程序显示工厂在选择供应商时，会评估到其社会责任表现。但是，基于令人满意的证据，主要受审核方没有完全尊重这个原则。

- 1.4 -** The factory had established the production capacity assessment procedure, but they had not assessed production capacity, workers' overtime working hours exceeded local law's requirement. This violated Performance Area 1: Social Management System and Cascade Effect 1.4

工厂已建立生产能力评估程序，但还未进行生产能力评估，导致员工的加班时间超过法规要求。根据执行领域1：社会管理体系和级联效应 1.4

#### Remarks from Auditee:

The factory management agreed the finding and no other comment.

### Performance Area 2 : Workers Involvement and Protection

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: B

Deadline date: 16/12/2020

#### GOOD PRACTICES:

None

#### AREAS OF IMPROVEMENT:

The factory established policy and provided training for workers to let them knew their personal rights. The grievance procedure was established, workers could communicate with worker representatives, and raise grievance through suggestion box. And the related policy had been posted in workshop to make workers aware of their rights and responsibilities. However, there were gaps had been identified in this performance area, workers did not completely knew BSCI COC content, the grievance procedure did not involve with its stakeholders.

工厂建立了制度并推行培训，以便让员工了解自身的权利。工厂建立了申诉机制，可以和员工代表沟通，或者通过意见箱反馈意见。并且已经通过在生产车间对相关政策进行公示，以便于让员工更好地了解这一政策。但是被审核方在该绩效区域有差距，员工并不完全了解BSCI COC内容，申诉程序没有涉及到利益相关方。

- 2.4 -** The factory had provided the social responsibility requirement and BSCI COC training for workers, however, the workers did not completely know the requirements of Amfori BSCI Codes per employee interview. This violated Performance Area 2: Workers Involvement and Protection 2.4.

工厂有给员工提供了社会责任要求和BSCI COC 培训，但是根据员工访谈员工并不完全了解Amfori BSCI守则的要求。根据执行领域2：工人参与和保护2.4

- 2.5 -** The established grievance mechanism did not include all interested parties, it was only applicable for internal part. In accordance with Performance Area 2: Workers Involvement and Protection 2.5.

工厂建立的申诉机制没有包含所有利益相关方，只是对工厂内部适用。根据执行领域2：工人参与和保护2.5

#### Remarks from Auditee:

The factory management agreed the finding and no other comment.

### Performance Area 3 : The rights of Freedom of Association and Collective Bargaining

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:

#### GOOD PRACTICES:

None

#### AREAS OF IMPROVEMENT:

The factory had established policy on the rights of freedom of association and collective bargain per BSCI COC requirements, worker representatives were elected freely, suggestion box was provided. Besides, the auditee has provided trainings to all workers regarding freedom of association and collective bargain. Workers could communicate with the worker representatives without interruption. All employees were not discriminated whether they were worker representatives or not.

工厂依据BSCI的行为准则建立了自由结社方面和集体谈判权的方针政策和程序文件，有自由选举员工代表，并设置了意见箱。此外工厂为所有员工提供了这方面的培训。员工可以不受干扰的和员工代表进行交流。此外所有员工无论他们是否是员工代表都不会受到歧视。

#### Remarks from Auditee:

None

Performance Area 4 : No Discrimination	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:
<b>GOOD PRACTICES:</b> None	
<b>AREAS OF IMPROVEMENT:</b> <p>The factory had established procedure and policy on non-discrimination per BSCI COC requirement, trainings regarding anti-discrimination were provided. All interviewed workers indicated that no discrimination case in the factory, no discriminate pregnancy testing was conducted for workers, and all employees were equal regardless of their race, age, gender and skin for overtime work, training and wage raising.</p> <p>工厂依据BSCI的行为准则建立了非歧视方面方针政策和程序文件，培训会涉及非歧视政策。员工访谈没有汇报歧视方面问题，工厂也没有要求员工验孕，所有员工不管什么种族，年龄，性别，肤色都一律平等享有加班机会、培训机会和加薪机会。</p>	
<b>Remarks from Auditee:</b> None	
Performance Area 5 : Fair Remuneration	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: B	Deadline date:16/01/2021
<b>GOOD PRACTICES:</b> None	
<b>AREAS OF IMPROVEMENT:</b> <p>The factory had established rule to ensure that all employees would be paid with enough wages per legal requirement. Based on document review, management interview and workers interview, the factory had provided the benefits such as paid annual leave, paid statutory holidays and etc for employees. Worker's wage was calculated in daily rate, they were paid with at least RMB 90 per day, which was higher than local minimum wage standard; the wage was paid at the 25th day of the next month by cash, the slip was provided; wages were paid in time. However, the factory did not ensure all workers were provided with all kinds of social insurance.</p> <p>工厂已经通过厂规来确保员工能依法获得足够的工资。根据文件审核，员工访谈及管理层访谈，被审核方已经依法为员工提供了带薪年假，带薪年假日等。员工工资为日薪工资，最低的日工资为RMB 90/天，高于当地最低工资水平；工厂会在每月25日通过现金支付员工上个月的工资，并且为员工提供工资条；没有发生拖欠工资的情况。但工厂没有确保所有员工获得所有类型的社保。</p> <p><b>5.5 -</b> According to the social insurance payment receipt of Sep 2020 provided by factory management, it was noted that only 46 out of 163 employees (28.22%) were provided with pension, unemployment, maternity and medical insurance, all 163 workers were provided with accident insurance, but not all workers were provided with all kinds of social insurance. Workers indicated that they were voluntary to participate in social insurance. Factory management agreed with the issue and would take corrective action as soon as possible. This violated Article 73 of the Labor Law of the People's Republic of China.</p> <p>根据厂方提供的2020年9月的社会保险缴费单据显示，工厂为46/163名员工(28.22%)提供了养老、生育、失业、医疗保险，为所有员工提供了工伤保险，但没有达到全员参保。员工表示是自愿参加社保的，工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第73条</p>	
<b>Remarks from Auditee:</b> The factory management agreed the finding and no other comment.	
Performance Area 6 : Decent Working Hours	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: D	Deadline date:16/01/2021
<b>GOOD PRACTICES:</b> None	
<b>AREAS OF IMPROVEMENT:</b> <p>The factory had established working hour policy, their regular working hours were 5 days per week and 8 hours per day. There were three working shifts for production workers, it was from 08:00-16:00, 16:00-24:00 and 24:00-08:00. The factory used IC card attendance system to record workers' attendance status. According to the sampled attendance records, employees did not work overtime in weekdays, the overtime hours were 8 hours per week, the maximum overtime hours were 40 hours per month. The maximum total working hours per week were 48 hours per week. The longest consecutive days worked were 6 days and had at least one day rest after 6 days. Workers were voluntary to participate in overtime work.</p> <p>工厂建立了工时管理制度，工厂的正班工时是每周5天，每天8小时。生产员工按照三个班次安排，分别为08:00-16:00，16:00-24:00，24:00-08:00。工厂采用IC卡考勤来记录员工的考勤状态。抽样的考勤里面，员工平时没有加班，每周加班8小时，每月加班最多40小时。每周的总工作时间最多是48小时。最多连续工作6天之后有至少一天休息。员工加班均为资源参加。</p> <p><b>6.2 -</b> According to the payroll and attendance records of 16 sample employees from Nov 2019, 16 sample employees from Feb 2020, 16 sample employees from recent paid month Aug 2020 and 5 records from unpaid full month of Sep 2020, it was noted that 16 out of 16 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Nov 2019, which was not in compliance with the legal requirement; 16 out of 16 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Feb 2020, which was not in compliance with the legal requirement; 16 out of 16 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Aug 2020, which was not in compliance with the legal requirement; All employees interviewed represented that they were voluntarily to work overtime and the production workload was acceptable. Factory management agreed with the issue and would take corrective action as soon as possible. This Violated Article 41 of the Labor Law of the PRC.</p> <p>根据工厂提供的工资考勤记录，抽样2019年11月16名员工，2020年2月16名员工，发薪月份2020年8月16名员工和未发薪月份2020年9月5名员工，显示16/16名员工在2019年11月的加班时间为40小时，超过每月加班时间不能超过36小时的法律规定；16/16名员工在2020年2月的加班时间为40小时，超过每月加班时间不能超过36小时的法律规定；16/16名员工在2020年8月的加班时间为40小时，超过每月加班时间不能超过36小时的法律规定；访谈员工表示自愿加班，工作强度也可以接受。工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第41条</p>	
<b>Remarks from Auditee:</b> The factory management agreed the finding and no other comment.	

## Performance Area 7 : Occupational Health and Safety

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date: 16/12/2020

### GOOD PRACTICES:

None

### AREAS OF IMPROVEMENT:

The committee of health and safety was set up by the factory, and EHS supervisor was responsible for the affairs of health and safety. Factory had conducted internal assessment for the risk of workshop accordingly to reduce potential health and safety risks. For fire safety, the factory equipped extinguishers in every workshop. Fire alarms, emergency lights and fire hydrant were available in the factory. All these Fire facilities were checked per month, fire drill for day shift and night shift was conducted. For mechanism safety, all operation instructions were set up; workers were well trained to operate it correctly. The factory also set up emergency procedure and trained sufficient first aiders for providing the service of first aid. The first aid box was also available in every workshop. The factory asked third party to conduct occupational health impact factors testing for workshops, workers were provided with free occupational health examination. Clean potable water was also provided, it was free for access.

工厂创建了员工的健康安全委员会，由EHS代表负责整体的健康与安全。工厂按照车间情况对工厂内部进行健康安全风险评估，消除潜在的安全风险。在消防安全方面，工厂给所有车间配备了灭火器，消防栓，应急灯、消防警铃。消防设施每月都会进行检查，有针对白班和夜班进行消防演习。在机械安全方面，工厂制定了相应的操作规程，并且给员工提供了操作培训。在急救政策方面，工厂制定了急救政策，工厂给每个车间配备了药箱，而且工厂有充足数量的急救员。工厂委托了第三方机构对车间职业危害因素进行了监测，并为员工提供了免费的职业健康体检。同时，工厂也提供了饮用水给员工，员工可随时喝水。

**7.3 -** It was noted that the health and safety risk assessment for workshops was conducted insufficiently. The risk assessment did not include the chemical safety risk in mixing workshop, such as the newly updated MSDS should be provided there. Factory management agreed with the issue and would take corrective action as soon as possible. This violated Performance Area 7: Occupational Health and Safety 7.3.

工厂为车间进行的健康安全风险评估不充分。风险评估没有包含配料车间使用的化学品的风险，比如应该提供最新的MSDS等。根据执行领域7：职业健康和安全 7.3. 工厂同意该问题并表示尽快改善。

**7.7 -** It was noted that there was no newly updated version MSDS onsite for hazardous chemical additive in mixing workshop. In accordance with Article 27 of the Regulation For Chemical Usage Safety in Work Place:

现场发现，配料车间没有张贴危险化学品添加剂的最新版本的MSDS。根据《工作场所安全使用化学品规定》第27条：

**7.23 -** No transportation was provided for workers, it was not applicable.

工厂没有为员工提供交通，不适用。

### Remarks from Auditee:

The factory management agreed the finding and no other comment.

## Performance Area 8 : No Child Labour

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:

### GOOD PRACTICES:

None

### AREAS OF IMPROVEMENT:

The factory had established procedures on no child labor, and remediation procedures are available in case child labor was found, the requirements were trained to all workers. Age verification mechanism was used upon recruitment to ensure all workers were over 16 years old, it was in line with local law requirement. Currently, no child labor was detected or reported.

工厂建立了不使用童工和童工补救措施程序文件，并将相关要求培训告知员工。招聘过程中工厂有年龄识别体系确保员工都满16岁，符合法规要求。审核过程没有发现童工或者汇报童工。

### Remarks from Auditee:

None

## Performance Area 9 : Special protection for young workers

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:

### GOOD PRACTICES:

None

### AREAS OF IMPROVEMENT:

The factory established policy to indicate that young worker would be protected properly, such as young worker would not be arranged in unreasonable position, regular health examination would be provided. The requirements were also trained to workers. According to document review, onsite observation and workers interview, no young worker was used in the factory currently.

工厂建立了政策，表明会合理保护未成年工人，比如不安排不合理的岗位，定期提供体检等。工厂有将相关要求培训告知员工。文件核实、现场观察、员工访谈确认，工厂目前没有使用到未成年工人。

### Remarks from Auditee:

None



Performance Area 10 : No Precarious Employment	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:
<b>GOOD PRACTICES:</b> None	
<b>AREAS OF IMPROVEMENT:</b> <p>Labor contracts were signed between the factory and each worker, the contracts statement included the description of working hours, training, rest time and leave, payment and payment method, which were in accordance with legal requirement and ILO. The factory had communicated all labor contract contents to all workers before they entered the factory. Meanwhile, the factory provided a copy of contract to every worker. No illegal worker was used in the factory, all of them were employed by the factory directly.</p> <p>工厂和每个员工均签订了劳动合同，劳动合同的内容包括工时，培训，休息时间和假期，报酬和支付条件，这些内容均符合法规以及国际标准。工厂有在员工入职前有告知员工合同的内容。同时工厂提供了一份劳动合同副本给员工。工厂无不合法用工形式存在，所有员工均为工厂自己招聘。</p>	
<b>Remarks from Auditee:</b> None	
Performance Area 11 : No Bonded Labour	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:
<b>GOOD PRACTICES:</b> None	
<b>AREAS OF IMPROVEMENT:</b> <p>The factory had established procedures on non-bond labor and all employees were freely to terminate their relationship with the factory with full wage paid. The factory provided dormitory for workers, they also could choose to live in their own house. No movement restriction area in the factory, they were voluntary to participate in overtime works. Interviewed workers indicated that no wage and ID card was withheld by the factory.</p> <p>工厂建立了无强迫劳动的程序文件，所有员工都可以自由终止劳动关系并拿到全额报酬。工厂有给员工提供了宿舍，员工可以自由选择回家住宿。车间没有设置限制活动区域，员工可以自由加班。员工表示没有发生扣押工资和身份证件的情况。</p>	
<b>Remarks from Auditee:</b> None	
Performance Area 12 : Protection of the Environment	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:16/12/2020
<b>GOOD PRACTICES:</b> None	
<b>AREAS OF IMPROVEMENT:</b> <p>The factory had established environmental management policy and procedures which included environment impact assessment, conformity assessment regards to environmental law, waste management, environment issue grievance, etc. The factory obtained environmental impact assessment report and approval from government department. Based on onsite observation, no obvious waste was released to factory surrounding during its production activities, no pollution was observed. The factory provided environmental protection knowledge training for workers.</p> <p>被审核方有建立环境政策，其中包括环境影响的评估，环保法规符合性识别评估，废弃物的管理，环保问题申诉等。工厂有获得建设项目的环评报告和政府部门的批复意见。工厂生产过程没有发现对周边环境排放明显的废弃物，没有发现污染情况。工厂有给员工提供了环保知识的培训。</p> <p><b>12.1 -</b> The factory had conducted environment impact assessment for the factory boundary, but the assessment did not include its production impact to other factories in the industrial park. In accordance with performance area 12: Protection of the environment. 12.1</p> <p>工厂有对周边环境进行环境影响评估，但没有评估其生产活动对园区内其他工厂影响。依据执行领域12：环境保护 12.1</p>	
<b>Remarks from Auditee:</b> The factory management agreed the finding and no other comment.	

**Performance Area 13 : Ethical Business Behaviour**

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:16/12/2020

**GOOD PRACTICES:**

None

**AREAS OF IMPROVEMENT:**

The factory had written procedures on Ethical Behaviour, which included prohibition of corruption, extortion or embezzlement, or any form of bribery, fraud and investigation of unethical behaviors etc. The factory had conducted the assessment on the potential ethic risks. During the audit, accurate records were provided for review, including payroll records, attendance records, certificates and reports. The effective business license was provided for review.

工厂已经建立了书面化的商业道德程序，其中包括风险评估，不正当收益，商业欺诈，不道德行为的调查等。被审核方对潜在的商业道德风险进行了风险评估。审核期间提供了准确的记录查看，包括工资考勤文件、证件和报告等。工厂有获得有效的营业执照。

- 13.4 -** It was noted that the factory had established personal privacy protection procedure, such as personal information privacy, financial privacy, etc, but trainings on personal privacy protection procedure was not provided to all employees. In accordance with Performance Area 13: Ethical Business Behaviour 13.4

审核发现尽管工厂建立了个人隐私保护程序，例如个人信息隐私、财务隐私等，但并未向所有员工提供个人隐私保护方面程序的培训。根据执行领域13：道德商业行为 13.4

**Remarks from Auditee:**

The factory management agreed the finding and no other comment.

**Summary**

Audit Type	Date	Audit Id	PA1	PA2	PA3	PA4	PA5	PA6	PA7	PA8	PA9	PA10	PA11	PA12	PA13	Overall Rating
Full Audit	15/10/2020	195058	B	B	A	A	B	D	A	A	A	A	A	A	A	C

**Producer Photos**



External photo(s) of the production unit(s)  
Attendance recorder.JPG



External photo(s) of the production unit(s)  
BSCI COC.JPG



External photo(s) of the production unit(s)  
Canteen building.JPG



External photo(s) of the production unit(s)  
Canteen.JPG



External photo(s) of the production unit(s)  
Dormitory building.JPG



External photo(s) of the production unit(s)  
Emergency light and exit sign.JPG



External photo(s) of the production unit(s)  
Emergency light testing.JPG



External photo(s) of the production unit(s)  
Evacuation plan.JPG



External photo(s) of the production unit(s)  
Eyewash station.JPG



External photo(s) of the production unit(s)  
Factory name.JPG



External photo(s) of the production unit(s)  
Finished goods.JPG



External photo(s) of the production unit(s)  
Fire alarm testing.JPG



External photo(s) of the production unit(s)  
Fire alarm.JPG



External photo(s) of the production unit(s)  
Fire extinguishers.JPG



External photo(s) of the production unit(s)  
Fire facility inspection record.JPG





External photo(s) of the production unit(s)  
Fire hydrant testing.JPG



External photo(s) of the production unit(s)  
Fire hydrant.JPG



External photo(s) of the production unit(s)  
First aid kit.JPG



External photo(s) of the production unit(s)  
Mask and earplugs for workers.JPG



External photo(s) of the production unit(s)  
Material warehouse.JPG



External photo(s) of the production unit(s)  
Mixing.JPG



External photo(s) of the production unit(s)  
Molding.JPG



External photo(s) of the production unit(s)  
No smoking sign.JPG



External photo(s) of the production unit(s)  
Packing.JPG



External photo(s) of the production unit(s)  
Potable water.JPG



External photo(s) of the production unit(s)  
PPE sign.JPG



External photo(s) of the production unit(s)  
Production building and factory gate.JPG



External photo(s) of the production unit(s)  
Raw material warehouse.JPG



External photo(s) of the production unit(s)  
Suggestion box.JPG



External photo(s) of the production unit(s)  
Testing.JPG



External photo(s) of the production unit(s)  
Toilet paper and sanitizer.JPG



External photo(s) of the production unit(s)  
Toilet.JPG



External photo(s) of the production unit(s)  
Warning sign.JPG



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Auditee :	<b>Better Care Plastic Technology Co., Ltd.</b>
Audit Date From :	<b>19/10/2020</b>
Audit Date To :	<b>20/10/2020</b>
Expiry Date of the Audit :	<b>Please refer to the producer profile in the amfori BSCI platform</b>
Auditing Company :	<b>BureauVeritas</b>
Auditor's Name(s) :	<b>Vera Wang(Lead), Andy Lu</b>
Auditing Branch (if applicable) :	

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This is an extract of the on line Audit Report. The complete report is available in the amfori BSCI Platform.  
Access [www.bsciplatform.org](http://www.bsciplatform.org), for entitled users only.

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This is an extract of the amfori BSCI Audit Report, which is available in the amfori BSCI Platform. © amfori, 2018 - The English version is the legally binding One.

## Rating Definitions



Rating	A combination of ratings per Performance Area where:	Consequence																																							
<b>A</b> <b>Very Good</b>	<ul style="list-style-type: none"><li>• Minimum 7 Performance Areas rated A</li><li>• No Performance Areas rated C, D or E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr></table>	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	B	A	A	A	A	A	A	A	B	B	B	B	B	B	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	A	A	A	A	A	A	A																													
A	A	A	A	A	A	A	A	A	A	B	B	B																													
A	A	A	A	A	A	A	B	B	B	B	B	B																													
<b>B</b> <b>Good</b>	<ul style="list-style-type: none"><li>• Maximum 3 Performance Areas rated C</li><li>• No Performance Areas rated D or E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td></tr><tr><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td></tr></table>	A	A	A	A	A	A	B	B	B	B	B	B	B	A	A	A	A	A	B	B	B	B	B	B	B	C	B	B	B	B	B	B	B	B	B	B	C	C	C	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	B	B	B	B	B	B	B																													
A	A	A	A	A	B	B	B	B	B	B	B	C																													
B	B	B	B	B	B	B	B	B	B	C	C	C																													
<b>C</b> <b>Acceptable</b>	<ul style="list-style-type: none"><li>• Maximum 2 Performance Areas rated D</li><li>• No Performance Areas rated E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>C</td><td>C</td><td>C</td><td>C</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td></tr><tr><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td></tr></table>	A	A	A	A	A	A	A	A	A	C	C	C	C	A	A	A	A	A	B	B	B	B	C	C	C	D	C	C	C	C	C	C	C	C	C	C	C	D	D	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	C	C	C	C																													
A	A	A	A	A	B	B	B	B	C	C	C	D																													
C	C	C	C	C	C	C	C	C	C	C	D	D																													
<b>D</b> <b>Insufficient</b>	<ul style="list-style-type: none"><li>• Maximum 6 Performance Areas rated E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>D</td><td>D</td><td>D</td></tr><tr><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td><td>D</td><td>E</td></tr><tr><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	A	A	A	A	D	D	D	A	A	A	B	B	B	C	C	C	D	D	D	E	D	D	D	D	D	D	D	E	E	E	E	E	E	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	A	D	D	D																													
A	A	A	B	B	B	C	C	C	D	D	D	E																													
D	D	D	D	D	D	D	E	E	E	E	E	E																													
<b>E</b> <b>Unacceptable</b>	<ul style="list-style-type: none"><li>• Minimum 7 Performance Areas rated E</li></ul> These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>A</td><td>A</td><td>B</td><td>B</td><td>C</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	E	E	E	E	E	E	E	A	A	B	B	C	D	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	amfori BSCI Participants shall closely oversee the auditee's progress as the producer may represent a higher risk than other business partners.
A	A	A	A	A	A	E	E	E	E	E	E	E																													
A	A	B	B	C	D	E	E	E	E	E	E	E																													
E	E	E	E	E	E	E	E	E	E	E	E	E																													
<b>Zero Tolerance</b>	A Zero Tolerance Issue was identified (see amfori BSCI System Manual Part V – Annex 5: amfori BSCI Zero Tolerance Protocol)	Immediate actions are required. The amfori BSCI Zero Tolerance Protocol is to be followed.																																							

**Main Auditee Information**



Name of producer :	Better Care Plastic Technology Co., Ltd.		
DBID number :	404438		
Audit ID :	195260		
Address :	FUQIAN XI ROAD WEST DISTRICT OF SHENZE INDUSTRIAL BASE, SHENZE COUNTY, Shijiazhuang		
Province :	Hebei	Country :	China
Management Representative :	Xiaoling Li		
Contact person:	Xiaoling li	Sector :	Non-Food
Industry Type :		Product group :	
Product Type :	Nitrile Gloves		

## Audit Details



Audit Range :	<input checked="" type="checkbox"/> Full Audit	<input type="checkbox"/> Follow-up Audit	
Audit Scope :	<input checked="" type="checkbox"/> Main Auditee	<input type="checkbox"/> Main Auditee & Farms	
Audit Environment :	<input checked="" type="checkbox"/> Industrial	<input type="checkbox"/> Agricultural	<input type="checkbox"/> Small Producer
Audit Announcement :	<input checked="" type="checkbox"/> Fully-Announced	<input type="checkbox"/> Fully-Unannounced	<input type="checkbox"/> Semi-Announced
Random Unannounced Check (RUC) :	No		
Audit extent (if applicable) :	none		
Audit interferences or contingencies (if applicable) :	none		
Overall rating :	C		
Need of follow-up :	Yes	If YES, by :	20/10/2021

### Rating per Performance Area (PA)

PA 1	PA 2	PA 3	PA 4	PA 5	PA 6	PA 7	PA 8	PA 9	PA 10	PA 11	PA 12	PA 13
B	B	A	A	B	D	A	A	A	A	A	B	A

### Executive summary of audit report

Factory name: Better Care Plastic Technology Co., Ltd 河北鸿泽塑胶科技有限公司  
 Factory address: FUQIAN XI ROAD WEST DISTRICT OF SHENZE INDUSTRIAL BASE, SHENZE COUNTY, Shijiazhuang Hebei - China  
 深泽县工业园区 (府前西路)  
 Business license number: 911301286920575093

The factory was established on July 10, 2009, it was mainly manufacturing nitrile gloves. The main production activities in the factory were mixing, forming, inspection and packing.

Per factory management interview, there was no peak season in the factory. Their capacity was 2,200,000,000 pcs per year.

The entire factory was consisted of one flat (part of 2F) production building, one flat (part of 3-storey) production building, one 6-storey dormitory building, one 2-storey canteen (idle).

The construction area used by auditee was about 54,630.37 S.Q meters.

There were totally 482 employees in the factory, including 55 non-production employees and 427 production employees. There were 183 male employees and 299 female employees. The youngest employee worked in the factory was 22 years old.

Production workers' working hours were recorded by face scan system with detailed time in and time out information. There was only one shift for office employees, it was from 08:00 to 12:00 and 13:30 to 17:30, three shifts for production employees, and it was from 00:00-08:00, 08:00-16:00, and 16:00-00:00. All workers were paid in hourly rate at the 20th day of next month by bank transfer.

According to the payroll and attendance records of 22 sample employees from Dec 2019, 22 sample employees from May 2020 and 22 sample employees from Aug 2020, it was noted that the regular wage of all sampled employees in these months was minimum RMB 11.25 per hour, the local minimum wage was RMB 1680 per month equivalent to RMB9.66/hour since Nov 1, 2019. All sampled employees were paid with 150% and 200% of regular wages for their work on weekdays and rest days respectively, which was in line with statutory requirement. No overtime works were noted in statutory holidays.

Additional 5 attendance records were sampled in Sep 2020 for working hour verification. The sampled records indicated that employees' maximum overtime hours was 0 hour a weekday, 8 hours a rest day, 0 hour a holiday, 8 hours a week and 40 hours a month in the testing months. The maximum weekly working hours were 48 hours. The longest consecutive working days were 6 days in the testing periods.

According to the social insurance payment receipt of Aug 2020 provided by factory management, it was noted that only 77 out of 482 employees (16%) were provided with unemployment, maternity and medical insurance, 133 out of 482 employees (28%) were provided with pension insurance and 482 out of 482 employees (100%) were provided with injury insurance. But not all workers were provided with all kinds of social insurance.

The attendance records were cross-checked against production records, attendance records, payroll records and confidential interviews, no inconsistencies regarding working hours were found.

At the end of the audit, a closing meeting was held with the factory representatives. All of the findings were disclosed and discussed and a corrective action plan was explained to the factory representatives, Mrs. Li Xiaoling / Vice GM and Mrs. Song Hongye / Worker Representative agreed with the findings and signed the corrective action plan.

Opening meeting factory representatives (name and titles)

Mr. Zhao Lipeng / Office director;

Mr. Li Ming / Safety director;

Mrs. Xu Lihua / QA director;

Mrs. Song Hongye / Worker Representative;

Remark:

1. There was no contractor used by the auditee, which makes the contractor license/permit not applicable.

2. There was no agency used by the auditee, which makes the agency labor contract not applicable.

3. The Government waivers were not applicable in the auditee.

4. The Collective bargaining agreements were not applicable in the auditee.

5. Audit Company: Bureau Veritas Consumer Products Service

Audit Company APSCA Number: 11600002

Lead Auditor Name: Vera Wang

APSCA Auditor Registered Number: RA 21700004

Member Auditor Name: Andy Lu

APSCA Auditor Registered Number: RA 21701159

## Ratings Summary



Auditee's background information			
Auditee's name :	<b>Better Care Plastic Technology Co., Ltd.</b>	Legal status :	<b>Limited company</b>
Local Name :	河北鸿泽塑胶科技有限公司	Year in which the auditee was founded :	<b>2009</b>
Address :	<b>FUQIAN XI ROAD WEST DISTRICT OF SHENZE INDUSTRIAL BASE, SHENZE COUNTY,</b>	Contact person (please select) :	<b>Xiaoling li</b>
Province :	<b>Hebei</b>	Contact's Email :	<b>renmin@hongray.com.cn</b>
City :	<b>Shijiazhuang</b>	Auditee's official language(s) for written communications :	<b>Chinese</b>
Region :	<b>North East Asia</b>	Other relevant languages for the auditee :	<b>None</b>
Country :	<b>China</b>	Website of auditee (if applicable) :	<b>None</b>
GPS coordinates :	<b>N38°18'97", E115°17'93"</b>	Total turnover (in Euros) :	<b>43091394.00</b>
Sector :	<b>Non-Food</b>	Of which exports % :	<b>90.00</b>
Industry :		Of which domestic market % :	<b>10.00</b>
If other, please specify :	<b>Nitrile Rubber</b>	Production volume :	<b>2,200,000,000 pcs/annually</b>
Product Group :		Production cost calculation :	<b>Yes</b>
If other, please specify :	<b>Nitrile Rubber Products</b>	Lost time injury calculation cost :	<b>No</b>
Product Type :	<b>Nitrile Gloves</b>		

Auditee's employment structure at the time of the audit		
Total number of workers :	<b>482</b>	Total number of workers in the production unit to be monitored (if applicable) :
		<b>0</b>
	MALE WORKERS	FEMALE WORKERS
Permanent workers	<b>183</b>	<b>299</b>
Temporary workers	<b>0</b>	<b>0</b>
In management positions	<b>34</b>	<b>21</b>
Apprentices	<b>0</b>	<b>0</b>
On probation	<b>0</b>	<b>0</b>
With disabilities	<b>0</b>	<b>0</b>
Migrants (national citizens)	<b>1</b>	<b>0</b>
Migrants (foreign citizens)	<b>0</b>	<b>0</b>
Workers on the permanent payroll	<b>183</b>	<b>299</b>
Production based workers	<b>149</b>	<b>278</b>
With shifts at night	<b>149</b>	<b>278</b>
Unionised	<b>0</b>	<b>0</b>
Pregnant	<b>-</b>	<b>0</b>
On maternity leave	<b>-</b>	<b>0</b>



**Finding Report**



**Performance Area 1 : Social Management System and Cascade Effect**

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B

Deadline date:20/12/2020

**GOOD PRACTICES:**

None.

**AREAS OF IMPROVEMENT:**

The overall observation showed that the auditee partially respected the requirement of this performance area. The auditee established an effective management to implement the BSCI Code of Conduct, and appointed a senior manager (Mrs. Li) to ensure that the BSCI values and principles were followed in a satisfactory manner. However, there was still a gap between the factory and amfori BSCI requirements in the following aspects. For example, the factory did not plan production capacity rationally, resulting in overtime exceeding legal requirements. 整体观察表明, 受审核方部分尊重这个执行领域的要求。被审核方已经建立了执行BSCI行为守则的有效管理体系, 并委派了高级经理(李女士)以确保其充分遵循BSCI价值和原则要求。发现工厂在系统执行方面和amfori BSCI要求仍有差距。比如: 工厂没有合理规划生产能力, 导致加班时间超过法律要求。

- 1.4 -** The factory had established the production capacity assessment procedure, but they had not assessed production capacity, workers' overtime working hours exceeded local law's requirement. This violated Performance Area 1: Social Management System and Cascade Effect 1.4  
工厂已建立生产能力评估程序, 但还未进行生产能力评估, 导致员工的加班时间超过法规要求。根据执行领域1: 社会管理体系和级联效应 1.4

**Remarks from Auditee:**

The factory agreed the finding and no other comment.

**Performance Area 2 : Workers Involvement and Protection**

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B

Deadline date:20/12/2020

**GOOD PRACTICES:**

None.

**AREAS OF IMPROVEMENT:**

The overall observation showed that the auditee partially respected the requirement of this performance area. Workers are freely and publicly to elect worker representative for once a year, the recent selected worker representative on Jan 4, 2020 and meeting on Sep 4, 2020. Employees could report grievance via suggestion box, hotline or email anonymously. With regard to the reported cases, the HR or worker representative would take time to handle the issues and no retaliation would be made. The factory had provided relevant documents for review. But based on those evidence, the main auditee partially respected this principle because defects were identified in this performance area. Follow findings listed in detailed information.

整体观察表明, 受审核方部分尊重这个执行领域的要求。员工每年至少有一次公开选举员工代表, 最近一次员工代表选举是在2020年1月4日, 最近一次会议举行在2020年9月4日。同时员工可以通过意见箱, 和邮箱来匿名申诉。对于所有上报的案例, 工厂人事部门会负责后续事宜调查和处理, 举报员工不会被打击报复。相关文件都有保留和提供查看。但是基于满意的证据, 被审核方部分遵守本原则, 具体详见审核发现。

- 2.4 -** The factory had provided the social responsibility requirement and BSCI COC training for workers, however, the workers did not completely know the requirements of Amfori BSCI Codes per employee interview. This violated Performance Area 2: Workers Involvement and Protection 2.4.  
工厂有给员工提供了社会责任要求和BSCI COC 培训, 但是根据员工访谈员工并不完全了解Amfori BSCI守则的要求。根据执行领域2: 工人参与和保护2.4
- 2.5 -** The established grievance mechanism did not include all interested parties, it was only applicable for internal part. In accordance with Performance Area 2: Workers Involvement and Protection 2.5.  
工厂建立的申诉机制没有包含所有利益相关方, 只是对工厂内部适用。根据执行领域2: 工人参与和保护2.5

**Remarks from Auditee:**

The factory agreed the finding and no other comment.

**Performance Area 3 : The rights of Freedom of Association and Collective Bargaining**

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

**GOOD PRACTICES:**

None.

**AREAS OF IMPROVEMENT:**

The overall observation showed that the auditee respected the requirement of this performance area. The auditee respect the right of workers to form and to bargain collectively, there were no isolated employee representatives, no discrimination, and the auditee encourage to enforce the communication between worker representative and workers.

整体观察表明, 受审核方尊重这个执行领域的要求。工厂尊重员工推举代表和协商参与工厂事务的权利, 工厂没有孤立员工代表, 没有区别对待, 工厂还鼓励员工代表多与员工沟通。

**Remarks from Auditee:**

None

**Performance Area 4 : No Discrimination**

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

**GOOD PRACTICES:**

None.

**AREAS OF IMPROVEMENT:**

The overall observation showed that the auditee respected the requirement of this performance area. The factory had established related non-discrimination policy and provided related training to all employees on Jan 13, 2020. All interview employees, esp. female interviewees told auditor there was no discrimination in the factory.

整体观察表明, 受审核方尊重这个执行领域的要求。工厂建立了明确的反歧视政策并且清楚地通过培训告知员工, 最近一次培训是在2020年1月13日。所有受访员工, 尤其是女性都向审核员反映没有歧视。

**Remarks from Auditee:**

None

**Performance Area 5 : Fair Remuneration**

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B

Deadline date:20/12/2020

**GOOD PRACTICES:**

None.

**AREAS OF IMPROVEMENT:**

The overall observation showed that the auditee partially respected the requirement of this performance area. The factory respected the local law requirements, and the wage related regulations were posted and clearly communicated to all employees. however, the factory management also admitted that they provided all 5 types of social insurances to part of employees. the factory did not conduct any survey or calculation of the local living wage.

整体观察表明, 受审核方部分尊重这个执行领域的要求。工厂遵守当地关于工资和福利的要求, 并且把相关法规要求张贴出来, 并且通过员工手册和开会让员工知晓。然而, 工厂为部分的员工提供5种社会保险, 工厂没有完成最低生活需求工资的调查和计算。

- 5.4 -** It was noted that the factory did not have the sense to evaluate the local living wage, and they did not conduct any survey or calculation of the local living wage before the audit. In accordance with Performance Area 5: Fair Remuneration 5.4

工厂没有意识去评估当地的最低生活需求工资, 也没有在审核前完成最低生活需求工资的调查和计算。根据执行领域5: 公平报酬 5.4

- 5.5 -** According to the social insurance payment receipt of Aug 2020 provided by factory management, it was noted that only 77 out of 482 employees (16%) were provided with unemployment, maternity and medical insurance, 133 out of 482 employees (28%) were provided with pension insurance and 482 out of 482 employees (100%) were provided with injury insurance. But not all workers were provided with all kinds of social insurance. Workers indicated that they were voluntary to participate in social insurance. Factory management agreed with the issue and would take corrective action as soon as possible. This violated Article 73 of the Labor Law of the People's Republic of China.

根据厂方提供的2020年8月的社会保险缴费单据显示, 工厂为77/482名员工(16%)提供了生育, 失业, 医疗保险, 工厂为133/482名员工(28%)提供了养老保险, 工厂为482/482名员工(100%)提供了工伤保险, 但没有达到全员参保。员工表示是自愿参加社保的, 工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第73条

**Remarks from Auditee:**

The factory agreed the finding and no other comment.

**Performance Area 6 : Decent Working Hours**

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: D

Deadline date:20/12/2020

**GOOD PRACTICES:**

None

**AREAS OF IMPROVEMENT:**

The factory partially respect this performance area. The factory respected local law related to normal working hours. The factory did not respect the overtime hours policy. The factory had clearly communicated working hour policy to all employees through training. Interviewed employees confirmed that they could choose to overtime working or not.

工厂部分尊重这个执行领域。工厂尊重了基本的正常工作时间规定, 没有尊重加班时间的规定, 工厂向员工传达了工厂关于工作时间的政策。面谈的员工证实加班是自愿的。

- 6.2 -** According to the payroll and attendance records of 22 sample employees from Dec 2019, 22 sample employees from May 2020, 22 sample employees from recent paid month Aug 2020 and 5 records from unpaid full month of Sep 2020, it was noted that 22 out of 22 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in May 2020, which was not in compliance with the legal requirement; 22 out of 22 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Aug 2020, which was not in compliance with the legal requirement. All employees interviewed represented that they were voluntarily to work overtime and the production workload was acceptable. Factory management agreed with the issue and would take corrective action as soon as possible. This Violated Article 41 of the Labor Law of the PRC.

根据工厂提供的工资考勤记录, 抽样2019年12月22名员工, 2020年5月22名员工, 发薪月份2020年8月22名员工和未发薪月份2020年9月5名员工, 显示 22/22名员工在2020年5月的加班时间为40小时, 超过每月加班时间不能超过36小时的法律规定; 22/22名员工在2020年8月的加班时间为40小时, 超过每月加班时间不能超过36小时的法律规定。访谈员工表示自愿加班, 工作强度也可以接受。工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第41条

**Remarks from Auditee:**

The factory agreed the finding and no other comment.

## Performance Area 7 : Occupational Health and Safety

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:20/11/2020

### GOOD PRACTICES:

None.

### AREAS OF IMPROVEMENT:

The overall observation showed that the auditee partially respected the requirement of this performance area. The auditee established fire safety policy, the emergency evacuation plan. The factory conducted twice fire drills each year on Oct 21, 2019 and May 25, 2020. All employees participated in the fire drill. The factory conducted both day and night shifts fire drills to ensure that all workers and all shifts participated in the fire drill. The auditee basically complied with occupational health and safety (OHS) regulations. Further, the auditee provided safety training to employees. However, some health and safety issues were noted onsite.

整体观察表明,受审核方部分尊重这个执行领域的要求。被审核方建立了消防程序文件,应急预案等,对员工进行安全培训等。工厂每年进行两次消防演习分别在2019年10月21日和2020年5月25日。所有员工均参加了消防演习,工厂进行了白天和夜间的消防演习,确保所有工人,所有班次均参与演习。被审核方基本遵守了适合其业务活动的职业健康与安全法规。但被审核方现场仍然有一些健康安全问题的点。

**7.1 -** It was noted that no specific full-time or part-time safety production management personnel was assigned in the factory, which with 482 employees for production. In accordance with Article 21 of Law of the People's Republic of China on Production Safety  
审核员发现工厂的生产员工人数为482人,并未配备专职或者兼职的安全生产管理人员。根据《中华人民共和国安全生产法》第二十一条

**7.3 -** It was noted that the risk assessment for safe, healthy and hygienic working conditions was not conducted sufficiently. The risk assessment did not cover all production activities, workplaces, machinery, equipment, chemicals, tools and processes and regular monitoring and testing. In accordance with Performance Area 7: Occupational Health and Safety-7.3

工厂为车间岗位进行风险评估不充分。风险评估没有涵盖所有生产活动、生产车间、机器、设备、化学品、工具和过程,没有包括定期监控和检测。根据执行领域7:职业健康和安全-7.3

**7.6 -** It was noted that one employee working in the forming workshop did not wear earplugs provided by the factory. The factory had established PPE procedure and provided PPE training for employees. Factory management agreed with the issue and would take corrective action as soon as possible. In accordance with Article 42 of Law of the People's Republic of China on Production Safety.

审核员发现工厂成型车间1名员工没有佩戴工厂提供的耳塞。工厂制定了PPE的程序,并为员工提供了PPE培训。工厂同意该问题并表示尽快改善。根据《中华人民共和国安全生产法》第42条。

**7.11 -** The factory management was unable to provide the fire acceptance check of one flat (part of 3-storey) production building for review. The total construction of all buildings were about 20300.47 square meters. The factory had installed sufficient fire extinguishers and fire hydrants in the buildings. Remark: The entire factory was consisted of one flat (part of 2F) production building, one flat (part of 3-storey) production building, one 6-storey dormitory building, one 2-storey canteen. In accordance with Article 13 of the Construction Project Fire Safety Supervision and Management Regulation. In accordance with Article 24 of the Construction Project Fire Safety Supervision and Management Regulation (Extract)  
厂方未能提供1栋1层局部三层的生产楼的消防验收合格证明。总的建筑面积约为20300.47平方米。工厂在厂房安装了足够的灭火器和消防栓。备注:工厂有1栋1层局部2层的生产厂房,1栋1层局部3层的生产厂房,1栋6层的宿舍,1栋2层的餐厅。根据《建设工程消防监督管理规定》第13条根据《建设工程消防监督管理规定》第24条(节选)

### Remarks from Auditee:

The factory agreed the finding and no other comment.

## Performance Area 8 : No Child Labour

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

### GOOD PRACTICES:

None.

### AREAS OF IMPROVEMENT:

The factory fully respect this performance area. The factory established its child labor forbidden policy. The factory had conducted relevant training for all workers on Jan 13 2020. It was noted that the HR related clerk had to check the ID and age during the hiring process. Through management interview, worker representative interview and employee interview, all knew the child labor forbidden policy and confirmed no child labor in the factory. The youngest employee was 22 years old.

工厂充分尊重这个执行领域。工厂建立了禁止童工政策。工厂为所有的员工在2020年1月13日进行了培训。负责招聘的相关HR人员知道他们必须严格核实新员工的年龄。通过员工、员工代表和管理层访谈都证实清楚的知晓禁止童工政策并且确定工厂没有童工。最小的工人是22岁。

### Remarks from Auditee:

None

## Performance Area 9 : Special protection for young workers

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

### GOOD PRACTICES:

None

### AREAS OF IMPROVEMENT:

The factory fully respect this performance area. There were not young workers in this factory. However, the factory had established related policies to ensure young workers' working time and not to contact with hazardous materials and harmful job. Worker representative stated that the factory held training and meetings to pay attention to young workers issues.

工厂充分尊重这个执行领域。审核发现工厂没有未成年工。但工厂建立了完整的未成年工保护政策,包括工作时间和禁止未成年工接触有毒化学品和有害工种等等。员工代表还表示,会举行定期的会议,来提醒未成年工问题。

### Remarks from Auditee:

None

Performance Area 10 : No Precarious Employment	
Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A	Deadline date:
<b>GOOD PRACTICES:</b> None.	
<b>AREAS OF IMPROVEMENT:</b> Based on satisfactory evidence, the main auditee fully respects this principle because: The factory had established clear recruit policies to respect local law requirements. Confirmed through employee and employee representative interview, they need to sign standard labor contracts with factory and they kept one labor contract. 基于令人满意的证据, 被审核方充分尊重BSCI的本条原则, 工厂建立了清楚地招聘程序来遵守当地的法规要求。通过员工和员工代表面谈, 确认所有员工进厂时必须签标准的劳动合同, 并且他们自己都留有一份合同。	
<b>Remarks from Auditee:</b> None	
Performance Area 11 : No Bonded Labour	
Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A	Deadline date:
<b>GOOD PRACTICES:</b> None.	
<b>AREAS OF IMPROVEMENT:</b> Based on satisfactory evidence, the main auditee fully respects this principle because: The factory established policies to forbidden bonded labour. Confirmed through employee and employee representative interview, no physical or verbal abuse was noted with the factory. 基于令人满意的证据, 被审核方充分尊重BSCI的本条原则, 工厂建立了禁止强迫员工政策。通过员工和员工代表面谈, 确认工厂不存在体罚和口头侮辱。但通过员工访谈, 审核员发现工厂员工对工厂相关的惩戒条款不了解。	
<b>Remarks from Auditee:</b> None	
Performance Area 12 : Protection of the Environment	
Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B	Deadline date:20/12/2020
<b>GOOD PRACTICES:</b> None.	
<b>AREAS OF IMPROVEMENT:</b> The main auditee partial respects this principle because: The overall observation showed that the auditee basically fulfilled the requirement of this performance area. The auditee continuously identified the significant impacts and environmental implications associated to its activity, and established the proper procedure to ensure integration of local environmental law into the business performance. The assessment did not include its production impact to other factories in the industrial park. 被审核方部分尊重BSCI的本条原则, 整体观察表明, 受审核方基本满足这个区的要求。被审核方持续识别其商业活动的重大影响及对环境造成的后果, 并且建立了合适程序来确保其商业模式中结合了当地环境法规。但是, 工厂没有评估其生产活动对园区内其他工厂影响。 <b>12.1 -</b> The factory had conducted environment impact assessment for the factory boundary, but the assessment did not include its production impact to other factories in the industrial park. In accordance with performance area 12: Protection of the environment. 12.1 工厂有对周边环境进行环境影响评估, 但没有评估其生产活动对园区内其他工厂影响。 依据执行领域12: 环境保护 12.1	
<b>Remarks from Auditee:</b> The factory agreed the finding and no other comment.	
Performance Area 13 : Ethical Business Behaviour	
Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A	Deadline date:20/12/2020
<b>GOOD PRACTICES:</b> None.	
<b>AREAS OF IMPROVEMENT:</b> The main auditee partial respects this principle because: The factory had established its ethic policy and none of any act of corruption, or any form of bribery in its activity was noticed during this audit. Training and meeting were regularly held, especially for the business and sourcing departments. The factory had established personal privacy protection procedure, but trainings on personal privacy protection procedure was not provided to all employees. 被审核方部分尊重BSCI的本条原则, 工厂制定了相关的廉政政策并且在审核过程中并没有发现任何腐败或贿赂的商业行为。工厂举办定期的会议和培训给相关的人员, 尤其重点是业务和采购部门。工厂已经制定了员工隐私的保护程序, 但是没有提供相关的培训给所有员工。 <b>13.4 -</b> It was noted that the factory had established personal privacy protection procedure, such as personal information privacy, financial privacy, etc, but trainings on personal privacy protection procedure was not provided to all employees. In accordance with Performance Area 13: Ethical Business Behaviour 13.4 审核发现尽管工厂建立了个人隐私保护程序, 例如个人信息隐私、财务隐私等, 但并未向所有员工提供个人隐私保护方面程序的培训。 根据执行领域13: 道德商业行为 13.4	
<b>Remarks from Auditee:</b> The factory agreed the finding and no other comment.	

## Summary



Audit Type	Date	Audit Id	PA1	PA2	PA3	PA4	PA5	PA6	PA7	PA8	PA9	PA10	PA11	PA12	PA13	Overall Rating
Full Audit	19/10/2020	195260	B	B	A	A	B	D	A	A	A	A	A	B	A	C



**Producer Photos**



External photo(s) of the production unit(s)  
7.6 not using earplug.JPG



External photo(s) of the production unit(s)  
assembly point.JPG



External photo(s) of the production unit(s)  
attendance machine.JPG



External photo(s) of the production unit(s)  
BSCI COC.JPG



External photo(s) of the production unit(s)  
canteen.JPG



External photo(s) of the production unit(s)  
dormitory inside.JPG



External photo(s) of the production unit(s)  
drinking water machine.JPG



External photo(s) of the production unit(s)  
electrical box.JPG



External photo(s) of the production unit(s)  
emergency light and exit sign testing.JPG



External photo(s) of the production unit(s)  
emergency light and exit sign.JPG



External photo(s) of the production unit(s)  
evacuation plan.JPG



External photo(s) of the production unit(s)  
eye-washing machine.JPG



External photo(s) of the production unit(s)  
factory building.JPG



External photo(s) of the production unit(s)  
factory gate.JPG



External photo(s) of the production unit(s)  
factory name.JPG





External photo(s) of the production unit(s)  
finished warehouse.JPG



External photo(s) of the production unit(s)  
fire alarm testing.JPG



External photo(s) of the production unit(s)  
fire alarm.JPG



External photo(s) of the production unit(s)  
fire extinguisher.JPG



External photo(s) of the production unit(s)  
fire hydrant testing.JPG



External photo(s) of the production unit(s)  
first aid box.JPG



External photo(s) of the production unit(s)  
forming.JPG



External photo(s) of the production unit(s)  
inspecting.JPG



External photo(s) of the production unit(s)  
mixing.JPG



External photo(s) of the production unit(s)  
no smoking sign.JPG



External photo(s) of the production unit(s)  
occupational hazardous notification card.JPG



External photo(s) of the production unit(s)  
packing.JPG



External photo(s) of the production unit(s)  
raw material warehouse.JPG



External photo(s) of the production unit(s)  
road name.JPG



External photo(s) of the production unit(s)  
suggestion box.JPG



External photo(s) of the production unit(s)  
toilet.JPG