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EU DECLARATION OF COMFORMITY

We, HN Medical Group Company Limited (Thailand)

Head Office Address:

498/188 Sammakorn Avenue. Ramindra, Ta Raeng, Bangkhen District. Bangkok, 10220 Thailand

Hereby declare that the following product, meet the provisions of

Medical Devices Directive (EU) 93/42/EEC for ANNEX I & III

Commission Regulation (EU) 10/2011 ANNEX II & III

Commission Regulation (EU) 2016/1416 & (EU) 2017/752

Manufacturing Site: HN Medical Group Company Limited (Thailand)

99/9 Moo 16 Nongheang, Panusnikom, Chonburi 20140 Thailand

EU Representative / Distribution Partner : MEDYBIRD LIMITED (UK)

2nd Floor, Bollin House, Bollin Walk, Wilmslow SK9 1DP United Kingdom

Application Standard(s)

EN 1186-2&3:2002, EN 455-1:2000, EN 455-2:2015, #EN ISO 21171:2006, #SATRA SOP CAT-015, #SATRA SOP CAT-035 and EN 455 Part 1,2,3 by TUV Rheinland. ISO9001:2015 (GSCS 200110-82) and ISO13486:2016 (GSCS 200110-83)

Product Description

Brand Name	Product	Size	Product Sold
M+D Disposable Nitrile Gloves	Acrylonitrile Butadiene Rubber		HN202001
KLEANSE Disposable Nitrile Gloves	Powder-free Disposable Gloves	XS (5-6); S (6-7);	HN202002
EXCEL Disposable Nitrile Gloves	(Non-Sterile)	M (7-8); L (8-9);	HN202003
MEDYBIRD(UK) Nitrile Disposable Gloves		XL (9-10)	MD202007

This declaration applies to all products manufactured identical to submitted for testing and assessment of compliance of the product with the requirement relating to safety standards listed above was performed by HN Medical Group Co.,Ltd. EU/REP - MEDYBIRD(UK) LIMITED. The conformity to type based on quality assurance of the production process under surveillance of the report reference number **CHM0300325/2029** by SATRA Technology Centre Ltd; and the report job number **242026551** by TUV Rheinland.

We explicitly designate SATRA Technology Centre Ltd. to act as our sole Authorized Representative in the European Union for the above indicated products.

Signature:



**HN Medical
Group Co.,Ltd.**

Divari Varintip
Managing Director

#SATRA SOP CAT-015 – Migration of metal elements (Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Zn) into 3% acetic acid. Quantification by ICP- OES.

Sample tested:	Element (mg/kg of foodstuffs)								
	Al	Ba	Co	Cu	Fe	Li	Mn	Ni	Zn
Unreferenced nitrile gloves									
3% Acetic Acid	<0.1	<0.1	<0.05	<0.05	0.16	<0.1	<0.1	<0.02	3.3
Specific migration limit	1*	1	0.05	5	48	0.6	0.6	0.02**	5*

*Commission regulation (EU) 2016/1416, requirements for aluminium and zinc applied from 14th September 2018.

**Commission regulation (EU) 2017/752, requirements for nickel applied from 19th May 2019.

Results are the mean of triplicate determinations

Customer details: Medybird Limited
Second Floor, Bollin House
Bollin Walk
Wilmslow
SK9 1DP

SATRA reference: CHM0300325/2029/LC
/B

Your reference:

Date of report: 22nd October 2020

Samples received: 28th August and 8th
September 2020

Date(s) work carried out: 18th September to 22nd
October 2020

TECHNICAL REPORT

Subject: Determination of removable surface powder in accordance with EN ISO
21171:2006 on samples of unreferenced nitrile gloves

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

Report signed by: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of unreferenced nitrile gloves were received on the 28th August 2020 for the determination of removable surface powder in accordance with EN ISO 21171:2006.

The gloves are manufactured by:

HN Medical Group Co.,Ltd.
99/9 Moo 16 Nongheang
Panusnikom, Chon Buri
Thailand 20140

SAMPLES SUBMITTED:



Samples of unreferenced nitrile gloves

TESTS REQUIRED:

- EN ISO 21171:2006 – Medical gloves – Determination of removable surface powder. Method B – Procedure for “powder free” gloves other than surgeon’s gloves

CONCLUSION:

The of unreferenced nitrile gloves were tested in accordance with EN ISO 21171:2006 method B and were found to contain 0.7 mg residual powder per glove and therefore can be classified as powder free gloves

RESULTS:

EN ISO 21171:2006 – Medical gloves – Determination of removable surface powder

Sample	Method	Mass of powder per glove (mg)
Unreferenced nitrile gloves	B	0.7
Requirement (clause 4.4)	≤ 2.0 mg for a 'powder-free' glove	

Method B – The result is based on one replicate of 5 gloves for each glove type

Customer details: Medybird Limited
Second Floor, Bollin House
Bollin Walk
Wilmslow
SK9 1DP

SATRA reference: CHM0300325 /2029
/SPT

Your reference:

Date of report: 16 October 2020

Samples received: 28 August 2020

Date(s) work carried out: Between 7 and 14
October 2020

TECHNICAL REPORT

Subject: Testing of unreferenced nitrile gloves in accordance with EN 455-1: 2000 and EN 455-2: 2015

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked \neq fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

Report signed by: Adam Mortiboys
Position: Team Leader
Department: Safety Product Testing

Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 455-1: 2000 and EN 455-2:2015

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
unreferenced nitrile gloves	7 (S) – 9 (L)	Blue	Size: 7 (S) Weight: 3.5g



Conclusion

Standard	Clause / Property	Result
EN 455-1: 2000	5 Watertightness test for the detection of holes	Pass
EN 455-2: 2015	4.2 Length	Pass
	4.3 Width	Pass
	5.2 Force at break	Pass requirements B and C
	5.3 Force at break after challenge testing	Pass requirements B and C

Testing

Samples were tested as received, and were conditioned to the individual requirements of each clause as stated in the standards.

Requirements

EN 455-1: 2000 General Inspection Level I requirements, sample code L, AQL 1.5 using table 2A of ISO 2859-1: 1999

Batch Size	Number of gloves to be tested	Accept	Reject
Not stated	200	7 failures	8 failures

EN 455-2:2015 Dimensions of examination/procedure gloves

Size	Median length (mm)	Median width (mm)
Extra small	≥ 240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra large		≥ 110
Length measured according to figure 1 of EN 455-2:2015 Width measured according to figure 1 of EN 455-2:2015 The width requirements are for gloves from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials		

Requirements for EN 455-2:2015 Force at Break

Median Values of Force at Break (N)			
	Surgical gloves a)	Examination / Procedure Gloves b)	

Test Results

EN 455-1: 2000 Test Results of gloves identified as unreferenced nitrile gloves

Clause / Test	Test Results	Result
5 Watertightness test for the detection of holes	Number of samples tested: 200 Number of leaks detected: 0	Pass

EN 455-2:2015 Test Results of gloves identified as unreferenced nitrile gloves

Clause / Test	Test Results				Result
	Sample	Size	Length mm	Width mm	
4.2 Length and 4.3 Width	1	7 (S)	242	82	Pass
	2	7 (S)	242	83	
	3	7 (S)	243	82	
	4	7 (S)	242	82	
	5	7 (S)	241	82	
	6	7 (S)	241	81	
	7	7 (S)	242	81	
	8	7 (S)	243	82	
	9	7 (S)	243	83	
	10	7 (S)	242	82	
	11	7 (S)	242	82	
	12	7 (S)	241	82	
	13	7 (S)	242	83	
	Median	-	242	82	

EN 455-2:2015 Test Results of gloves identified as unreferenced nitrile gloves

Clause / Test	Test Results				Result
	Sample	Size	Length mm	Width mm	
4.2 Length and 4.3 Width	1	8 (M)	248	86	Pass
	2	8 (M)	248	86	
	3	8 (M)	248	85	
	4	8 (M)	248	86	
	5	8 (M)	246	86	
	6	8 (M)	249	87	
	7	8 (M)	248	86	
	8	8 (M)	246	86	
	9	8 (M)	247	85	
	10	8 (M)	247	86	
	11	8 (M)	248	86	
	12	8 (M)	249	86	
	13	8 (M)	248	86	
	Median	-	248	86	

EN 455-2:2015 Test Results of gloves identified as unreferenced nitrile gloves

Clause / Test	Test Results				Result
	Sample	Size	Length mm	Width mm	
4.2 Length and 4.3 Width	1	9 (L)	254	103	Pass
	2	9 (L)	254	103	
	3	9 (L)	255	103	
	4	9 (L)	256	104	
	5	9 (L)	253	103	
	6	9 (L)	254	103	
	7	9 (L)	256	103	
	8	9 (L)	255	103	
	9	9 (L)	255	104	
	10	9 (L)	254	102	
	11	9 (L)	253	103	
	12	9 (L)	254	102	
	13	9 (L)	256	103	
	Median	-	254	103	

EN 455-2:2015 Test Results for as received gloves identified as unreferenced nitrile gloves

Clause / Test	Test Results					Result
	Sample	Single wall thickness mm (tf)	Thickness of dumbbell pieces mm (tx)	tf/tx	Force at break /N	
5.2 Force at Break	1	0.13	0.08	1.6	6.71	Pass requirements B and C only
	2	0.12	0.07	1.7	7.68	
	3	0.125	0.07	1.8	7.06	
	4	0.125	0.07	1.8	6.41	
	5	0.13	0.07	1.9	6.84	
	6	0.12	0.08	1.5	7.08	
	7	0.12	0.07	1.7	7.30	
	8	0.12	0.07	1.7	7.96	
	9	0.125	0.07	1.8	6.81	
	10	0.125	0.07	1.8	7.01	
	11	0.13	0.07	1.9	7.33	
	12	0.125	0.07	1.8	8.03	
	13	0.125	0.07	1.8	7.44	
	Median	-	-	-	7.08	
tf/tx \geq 0.9 No correction is required tf/tx < 0.9 Correction is required						

EN 455-2:2015 Test Results for after aged gloves identified as unreferenced nitrile gloves

Clause / Test	Test Results					Result
	Sample	Single wall thickness mm (tf)	Thickness of dumbbell pieces mm (tx)	tf/tx	Force at break /N	
5.2 Force at Break	1	0.135	0.06	2.3	6.77	Pass requirements B and C
	2	0.125	0.05	2.5	5.39	
	3	0.135	0.06	2.3	5.25	
	4	0.135	0.07	1.9	6.27	
	5	0.13	0.07	1.9	6.55	
	6	0.125	0.07	1.8	6.46	
	7	0.125	0.06	2.1	7.64	
	8	0.125	0.06	2.1	6.45	
	9	0.13	0.07	1.9	7.10	
	10	0.13	0.07	1.9	5.09	
	11	0.135	0.05	2.7	6.32	
	12	0.135	0.06	2.3	7.14	
	13	0.13	0.06	2.2	6.94	
	Median	-	-	-	6.46	
tf/tx ≥ 0.9 No correction is required tf/tx < 0.9 Correction is required						

Additional Information / Notes

Additional uncertainty of measurement information

Clause / Test	Property	UoM
5 Watertightness	Time (s)	± 1.0 s
4.2 Length and 4.3 Width	Measurement (mm)	± 1.2 mm
5.2 Force at break	Force (N)	± 4.2%