

SETino®



NITRILE GLOVES



**EN
455**



EU DECLARATION OF CONFORMITY

Manufacturer:

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260
Hebei, China
Tel.: +86-311-83610904
Fax: +86-311-83610904

whose single Authorized Representative:

Caretechion GmbH
Niederrheinstr. 71, 40474 Düsseldorf,
Germany
DIMDI Code: DE/0000048026
Tel/Fax: 0211 3003 6618
Email: info@caretechion.com

We, the manufacturer, herewith declare that the products

Disposable Nitrile Examination Glove

UMDNS-Code: 11-882

SETINO-Code: N-1

Meet the provisions of MDD 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of
Medical Devices Directive 93/42/EEC and Annex VIII of Medical Devices Regulation 2017/745 EU



The Declaration of conformity is valid in connection with the release document for the respective batch of
produced devices.

The product concerned has been manufactured under a quality management system according to
Annex VII of Medical Devices Directive 93/42/EEC.

Following the procedure relating to the EC Declaration of Conformity set out in Annex VIII of Medical
Devices Regulation 2017/745 EU.

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, China.

Jinzhou China 2020-04-01

Place, date

GM: 
Legally binding signature, Function



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under its sole responsibility declares, that the personal protective equipment specified below:

Disposable Nitrile Glove
NPF2001-XS, NPF2002-S, NPF2003-M, NPF2004-L, NPF2005-XL
SETINO CODE: N-1

was classified in category III. - PPE (EU) 2016/425 II. according to its annex
EN ISO 374-1: 2016; EN 374-4: 2013; EN ISO 374-5: 2016; EN 420:2003 + A1:2009

EN ISO 374-5:2016



EN ISO 374-1:2016/Type B



The protective equipment complies with the requirements of Regulation 2016/425 (EU) and the harmonized European standards EN ISO 374-1: 2016, EN ISO 374-5: 2016, EN 374-4: 2013, and identical to PPE covered by EU type examination (Module B); certificate number:
2777/11050-02/E00-00

Issuing certification body:

SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland
Notified Body: 2777

According to module C2 for PPE, a conformity assessment procedure is carried out under the supervision of the notified body, supervising:

SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland
Notified Body: 2777

Setino Hungary Kft.
Száva 4/B 1107. Budapest, Hungary

2020.10.16

Place, date


[Signature]
Signature

EU Type-Examination Certificate

Certificate number: 2777/11050-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference: Description:

NPF2001-XS
NPF2002-S
NPF2003-M
NPF2004-L
NPF2005-XL

Disposable nitrile glove (blue beaded ambidextrous)

Classification:**Sizes:**

6	XS
7	S
8	M
9	L
10	XL

EN ISO 374-1:2016 TYPE B

40% Sodium hydroxide
30% Hydrogen peroxide
37% Formaldehyde

Level

6
3
4

EN 374-4:2013**Degradation %**

-16.0
26.8
34.0

EN ISO 374-5:2016

Protection against bacteria and fungi
Protection against virus

Level

Pass
Pass

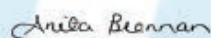
Standards/Technical specifications applied:

EN ISO 374-1:2016; EN 374-4: 2013; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:

SATRA: CHT0271907/1823/SPT/Issue 3, CHT0271907/1823/JS/A, CHT0271907/1823/JS/B, CHT0271907/1823.
SGS: HL50134/2019

Signed on behalf of SATRA:



Anita Brennan



Geoff Graham

Date first issued: 10/08/2018**Date of issue: 15/07/2019****Expiry date: 10/08/2023**

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.



PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to:

Shijiazhuang Hongray Group Co Ltd
South Tongda, East District
Jinzhou City
Hebei Province
China

This is to certify that the following products tested under SATRA reports referenced: STE0302530 & CHM0304519/2045/LC have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11050-02/E00-00	NPF 2001-2005	Disposable nitrile glove (Blue beaded ambidextrous)	EN ISO 3741:2016 Type B

Dated: 2nd December 2020

This certificate is
valid until:

December 2021

Signed By (Alan Weston)

For and on behalf of SATRA Technology
Europe Limited



The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

*SATRA Technology Europe Limited. Bracetown Business Park Clonree Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)*

Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

DISPOSABLE NITRILE GLOVES BOX - MD/PPE



240 x 120 x 65 mm



DISPOSABLE NITRILE GLOVES

CARTON - MD/PPE



340 x 250 x 255 mm

Box	Carton	Pallet	20GP	40GP	40HQ
100pcs	10 boxes	80 carton	1300 cartons	2700 cartons	3100 cartons

Box size (M): 240 x 120 x 65 mm
Carton size (M): 340 x 250 x 255 cm

S	M	L	XL
10%	40%	40%	10%

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