

Document Number : "redacted for public use"

Version: A/1

EU DECLARATION OF CONFORMITY

1) This declaration of conformity is issued under the sole responsibility of the manufacturer:

Company Name:		"redacted for public use"					
Address:		"redacted for public use"					
Product code:		XS-6	S-7	M-8	L-9	XL-10	XXL-11
	Blue	NGPF7000	NGPF7001	NGPF7002	NGPF7003	NGPF7004	NGPF7005
		NGV/B/H/P/ XE10013	NGV/B/H/P/ XE10014	NGV/B/H/P/ XE10015	NGV/B/H/P/ XE10016	NGV/B/H/P/ XE10017	NGV/B/H/P/ XE10018
		NGV/B/H/P/ XE20013	NGV/B/H/P/ XE20014	NGV/B/H/P/ XE20015	NGV/B/H/P/ XE20016	NGV/B/H/P/ XE20017	NGV/B/H/P/ XE20018
		SNV/B/H/P/ E10013	SNV/B/H/P/ E10014	SNV/B/H/P/ E10015	SNV/B/H/P/ E10016	SNV/B/H/P/ E10017	SNV/B/H/P/ E10018
		SNV/B/H/P/ E20013	SNV/B/H/P/ E20014	SNV/B/H/P/ E20015	SNV/B/H/P/ E20016	SNV/B/H/P/ E20017	SNV/B/H/P/ E20018
	White	WNPF7000	WNPF7001	WNPF7002	WNPF7003	WNPF7004	WNPF7005
		NGV/B/H/P/ XE10023	NGV/B/H/P/ XE10024	NGV/B/H/P/ XE10025	NGV/B/H/P/ XE10026	NGV/B/H/P/ XE10027	NGV/B/H/P/ XE10028
		NGV/B/H/P/ XE20023	NGV/B/H/P/ XE20024	NGV/B/H/P/ XE20025	NGV/B/H/P/ XE20026	NGV/B/H/P/ XE20027	NGV/B/H/P/ XE20028
		SNV/B/H/P/ E10023	SNV/B/H/P/ E10024	SNV/B/H/P/ E10025	SNV/B/H/P/ E10026	SNV/B/H/P/ E10027	SNV/B/H/P/ E10028
		SNV/B/H/P/ E20023	SNV/B/H/P/ E20024	SNV/B/H/P/ E20025	SNV/B/H/P/ E20026	SNV/B/H/P/ E20027	SNV/B/H/P/ E20028
	Violet	NGPF7000- V1	NGPF7001- V1	NGPF7002- V1	NGPF7003- V1	NGPF7004- V1	NGPF7005- V1
		NGV/B/H/P/ XE10033	NGV/B/H/P/ XE10034	NGV/B/H/P/ XE10035	NGV/B/H/P/ XE10036	NGV/B/H/P/ XE10037	NGV/B/H/P/ XE10038
		NGV/B/H/P/ XE20033	NGV/B/H/P/ XE20034	NGV/B/H/P/ XE20035	NGV/B/H/P/ XE20036	NGV/B/H/P/ XE20037	NGV/B/H/P/ XE20038
		SNV/B/H/P/ E10033	SNV/B/H/P/ E10034	SNV/B/H/P/ E10035	SNV/B/H/P/ E10036	SNV/B/H/P/ E10037	SNV/B/H/P/ E10038
		SNV/B/H/P/ E20033	SNV/B/H/P/ E20034	SNV/B/H/P/ E20035	SNV/B/H/P/ E20036	SNV/B/H/P/ E20037	SNV/B/H/P/ E20038
	Black	BNPF7000	BNPF7001	BNPF7002	BNPF7003	BNPF7004	BNPF7005
		NGV/B/H/P/ XE10043	NGV/B/H/P/ XE10044	NGV/B/H/P/ XE10045	NGV/B/H/P/ XE10046	NGV/B/H/P/ XE10047	NGV/B/H/P/ XE10048
		NGV/B/H/P/ XE20043	NGV/B/H/P/ XE20044	NGV/B/H/P/ XE20045	NGV/B/H/P/ XE20046	NGV/B/H/P/ XE20047	NGV/B/H/P/ XE20048
		SNV/B/H/P/ E10043	SNV/B/H/P/ E10044	SNV/B/H/P/ E10045	SNV/B/H/P/ E10046	SNV/B/H/P/ E10047	SNV/B/H/P/ E10048



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	SNV/B/H/P	SNV/B/H/P	SNV/B/H/P	SNV/B/H/P	SNV/B/H/P	SNV/B/H/P
	E20043	E20044	E20045	E20046	E20047	E20048

2) Disposable Nitrile Gloves (Blue; White; Violet; Black)



3)The object of the declaration described in point 2 is in conformity with the relevant Union harmonisation legislation: **Personal Protective Equipment Regulation (EU) 2016/425**

4)References to the relevant harmonised standards used, including the date of the standard or references to the other technical specification, including the date of the specification, in relation to which conformity is declared:

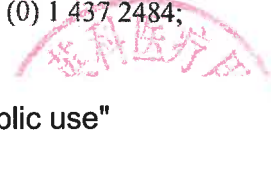
Standards/ Technical Specifications applied	EN ISO 21420:2020
	EN ISO 374-1:2016+A1:2018
	EN ISO 374-4:2019
	EN ISO 374-5:2016

5)Where applicable, the notified body SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland Tel:+00353 (0) 1 437 2484; Notified Body Number: 2777 performed the EU examination (Module B) and issued the EU type- examination certificate (Reference to that certificate: 2777/14815-03/E00-00)

6)Where applicable, the PPE is subject to the conformity assessment procedure (either conformity to type based on internal production control plus supervised product checks at random intervals (module C2) or conformity to type based on quality assurance of the production process (module D under surveillance of the notified body: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland Tel:+00353 (0) 1 437 2484; Notified Body Number: 2777

Signed for and on behalf of
Date of issue
Name, function

"redacted for public use"



Document Number : "redacted for public use"

Version: A/2

## EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

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Declares that the MDR described hereafter

*Product name and model:*

**Disposable Nitrile Exam Gloves**

**EMDN code: T01020204**

**Model:**XS/S/M/L/XL/XXL

**Product Code:** See the following annex I

**Basic UDI-DI:** 697306977NitrileFR

**SRN:** CN-MF-000002356

This declaration of conformity is issued under the sole responsibility of the manufacturer:

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Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016

EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-11:2017

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them,

The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII

Chapter III of the Regulation EU 2017/745 MDR. It bears the mark



We agree to develop, implement and maintain a documented post-production monitoring process



## Annex 1 product code

Color	Product Code
Blue	NGV/B/H/PEM10013-NGV/B/H/PEM10018
	NGV/B/H/PEM20013-NGV/B/H/PEM20018
	SNV/B/H/PE10013-SNV/B/H/PE10018
	SNV/B/H/PE20013-SNV/B/H/PE20018
White	NGV/B/H/PEM10023-NGV/B/H/PEM10028
	NGV/B/H/PEM20023-NGV/B/H/PEM20028
	SNV/B/H/PE10023-SNV/B/H/PE10028
	SNV/B/H/PE20023-SNV/B/H/PE20028
Voilet	NGV/B/H/PEM10033-NGV/B/H/PEM10038
	NGV/B/H/PEM20033-NGV/B/H/PEM20038
	SNV/B/H/PE10033-SNV/B/H/PE10038
	SNV/B/H/PE20033-SNV/B/H/PE20038
Black	NGV/B/H/PEM10043-NGV/B/H/PEM10048
	NGV/B/H/PEM20043-NGV/B/H/PEM20048
	SNV/B/H/PE10043-SNV/B/H/PE10048
	SNV/B/H/PE20043-SNV/B/H/PE20048
Pink	NGV/B/H/PEM10053-NGV/B/H/PEM10058
	NGV/B/H/PEM20053-NGV/B/H/PEM20058

Anhui 2021-10-30

Place, date

英科医疗用品有限公司  
Quality Manager

Legally binding signature, Function

英科医疗用品有限公司

Issued to



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Notified Body 2777

SATRA customer number: P21130

## EU Type-Examination Certificate

### Certificate number: 2777/22223-01/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. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

**Product reference:** NGX/S/TEXXXXX  
**Description:** Disposable Nitrile Gloves, Non-sterile

**Blue**

NGX/S/TE10014-NGX/S/TE10018  
NGX/S/TE20014-NGX/S/TE20018  
NGX/S/TE10F14-NGX/S/TE10F18  
NGX/S/TE20F14-NGX/S/TE20F18  
NGX/S/TE10P14-NGX/S/TE10P18  
NGX/S/TE20P14-NGX/S/TE20P18

**Violet**

NGX/S/TE10034-NGX/S/TE10038  
NGX/S/TE20034-NGX/S/TE20038  
NGX/S/TE10F34-NGX/S/TE10F38  
NGX/S/TE20F34-NGX/S/TE20F38  
NGX/S/TE10P34-NGX/S/TE10P38  
NGX/S/TE20P34-NGX/S/TE20P38

**Green**

NGX/S/TE10084-NGX/S/TE10088  
NGX/S/TE20084-NGX/S/TE20088  
NGX/S/TE10F84-NGX/S/TE10F88  
NGX/S/TE20F84-NGX/S/TE20F88  
NGX/S/TE10P84-NGX/S/TE10P88  
NGX/S/TE20P84-NGX/S/TE20P88

**Black**

NGX/S/TE10044-NGX/S/TE10048  
NGX/S/TE20044-NGX/S/TE20048  
NGX/S/TE10F44-NGX/S/TE10F48  
NGX/S/TE20F44-NGX/S/TE20F48  
NGX/S/TE10P44-NGX/S/TE10P48  
NGX/S/TE20P44-NGX/S/TE20P48

**Sizes:**  
7-11(S-XXL)

**Classification:**  
EN ISO 374-1:2016+A1:2018/Type B

(K) Sodium hydroxide 40%  
(P) Hydrogen peroxide 30%  
(T) Formaldehyde 37%  
(O) Ammonium hydroxide 25%

**Level**

6  
3  
6  
2

**EN ISO 374-4:2019  
Degradation %**

-30.1  
43.1  
-17.5  
-3.58

**EN ISO 374-5:2016**  
Protection against Bacterial and Fungi  
Protection against Viruses

**Level**

Pass  
Pass

Standards/Technical specifications applied:  
EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016

Technical reports/Approval documents  
SATRA: CHT0316811/2128, CHM0317791/2132, EN/A, CHM0317783/2132/LC, CHT0329910/2210, CHT0335653/2232,  
CHT0335234/2231, CHT0333675/2228  
SGS: GDHL2206007432HM, GDHL2200008535HM  
TUV: 7191208810-EEC21-WBH-CR2

Signed on behalf of SATRA

Geoff Graham

**Date first issued:** 29/08/2022  
**Date of issue:** 29/08/2022  
**Expiry date:** 29/08/2027



# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

"redacted for public use"

has been assessed by Intertek as conforming to the requirements of:

## ISO 13485:2016

The quality management system is applicable to:

Manufacture of non sterile medical examination NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) gloves.

**Certificate Number:**

0102138-01

**Initial Certification Date:**

June 01, 2020

**Date of Certification Decision:**

June 9, 2021

**Issuing Date:**

June 9, 2021

**Valid Until:**

June 8, 2024



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**Calin Moldovean**  
President, Business Assurance

Intertek Testing Services NA Ltd.,  
1829, 32nd avenue, Lachine, QC, H8T 3J1,  
Canada



