

Nitril Handschuhe CE 2777 Artikelnummer: WSNBR-01

• EN 455 – 1: 2020

• EN 455 – 2: 2015

EN 455 – 3: 2015

• EN ISO 374 – 1: 2016

EN ISO 374 – 2: 2019

• EN 16523 – 1: 2015

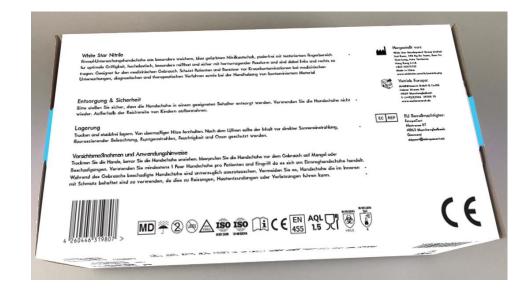
EN ISO 374 – 4: 2019

EN ISO 374 – 5: 2015

BS EN ISO 21420

ISO 16604: 2004







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Producer:

White Star Development Group Limited, Honkong

Produce in: China

EU REP:

EuropeCert Mönchengladbach

Sales Europa:

MARKENmerch GmbH & Co. KG Mönchengladbach

WHITE STAR DEVELOPMENT GROUP LIMITED

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NITRILE POWDER FREE EXAMINATION GLOVE SPECIFICATIONS

+‡+

PRODUCT DESCRIPTION

Material Nitrile

Surface Finishing Finger surface textured with light polymer coating on the donning side

Color Blue

Design Feature Ambidextrous, beaded cuff

Shelf Life Maximum 3 years from date of manufacture, and stored under recommended

conditions

Recommended Storage Conditions: The gloves shall maintain their properties when stored in a

dry condition. Direct sunlight should be avoided.

PERFORMANCE ATTRIBUTES (Sampling Plan – ISO 2859-1:1999; Single Inspection)							
Characteristics		Inspection Level	Acceptable Quality Level	Reference Standard			
Freedom from holes - Barrier		GI	1.5	ASTM 5151-08 EN 455-1			
Visual Defect	Major Visual Minor Visual	GI	2.5 4.0	Industry Practice			
Dimensions		S-2	4.0	ASTM D6319 EN 455-2			
Physical Properties		S-2	4.0	ASTM D6319 EN 455-2			
Residual Powder Content		N=5	N/A	ASTM D6124 EN 455-3			

PHYSICAL PROPERTIES					
Physical Feature	Size	Specification Limits	Reference Standard		
Length (mm)	All Sizes	Min. 230; Max. 240	ASTM D6319 EN 455-2		
	XS	70±10			
	M	80±10	ASTM D8319		
Average Palm Width (mm)	L	95±10	EN ISO 21420:2020		
' '	XL	110±10			
	XXL	130±10	Internal/Customer Specs		
	All Sizes	Middle Finger: 0.08	ASTM D6319		
Average Thickness (mm) +/-0.02		Palm: 0.08	EN ISO 21420:2020		
. , ,		Cuff: 0.06	Internal/Customer Specs		

PHYSICAL STRESS-STRAIN PROPERTIES					
Physical Property	Specification Limits				
1 Hysical 1 Toperty	Before Aging	After Aging	Reference Standard		
Elongation at break (%)	Min. 400	Min. 300	- ASTM D6319		
Tensile Strength (MPa)	Min. 11	Min. 11			
Force at Break	Median 6	Median 6	EN 455-2		
Residual Powder Content	N=5	≤2 mg per glove	ASTM D6124 EN 455-3		

REGULATORY STANDARDS					
ISO 9001	ISO 13485	ISO 10993-5			
ISO 10993-10	FDA 21 CFR 177.2600	EN 1186			
EN ISO 21420:2020	EN ISO 374-1:2016+A1:2018	EN 374-5:2016			

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Issued to

White Star Development Group Limited 2nd Floor, 49B Ng Ka Tsuen New Territories Hong Kong

SATRA customer number: P20308

EU Type-Examination Certificate

Certificate number: 2777/15456-02/E01-01

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.

WSNBR-01

Nitrile Examination Glove, Powder-Free

Colour: Blue

Sizes S/6, M/7, L/8, XL/9

EN ISO 374-1:2016+A1:2018 /Type C Level EN ISO 374-4:2019 Degradation % 40% Sodium Hydroxide (K)

EN ISO 374-5:2016

Protection against Bacteria and Fungi Protection against Viruses

Pass Pass

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

SATRA: CHT0300498/2030/issue 2, CHM0302486/2038/JS/A, CHM0302486/2038/JS/B, CHT0303908/2043. CHT0305556/2048

Signed on behalf of SATRA:





Quincey Brown

Date of issue: 12/01/2021

Expiry date: 14/12/2025

SATRA Technology Europe Limited. Bracetown Business Park. Clones. D15YN2P. Republic of Ireland.

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. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

- Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
- Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
- Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
- Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
- Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
- The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation
- 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
- 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, or UK government.
- 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 the applicable legislation (See note 11).
- 11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2018/425 of the European Parliament and of the council of 9th March 2018 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.





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