SHIELDskin XTREME™

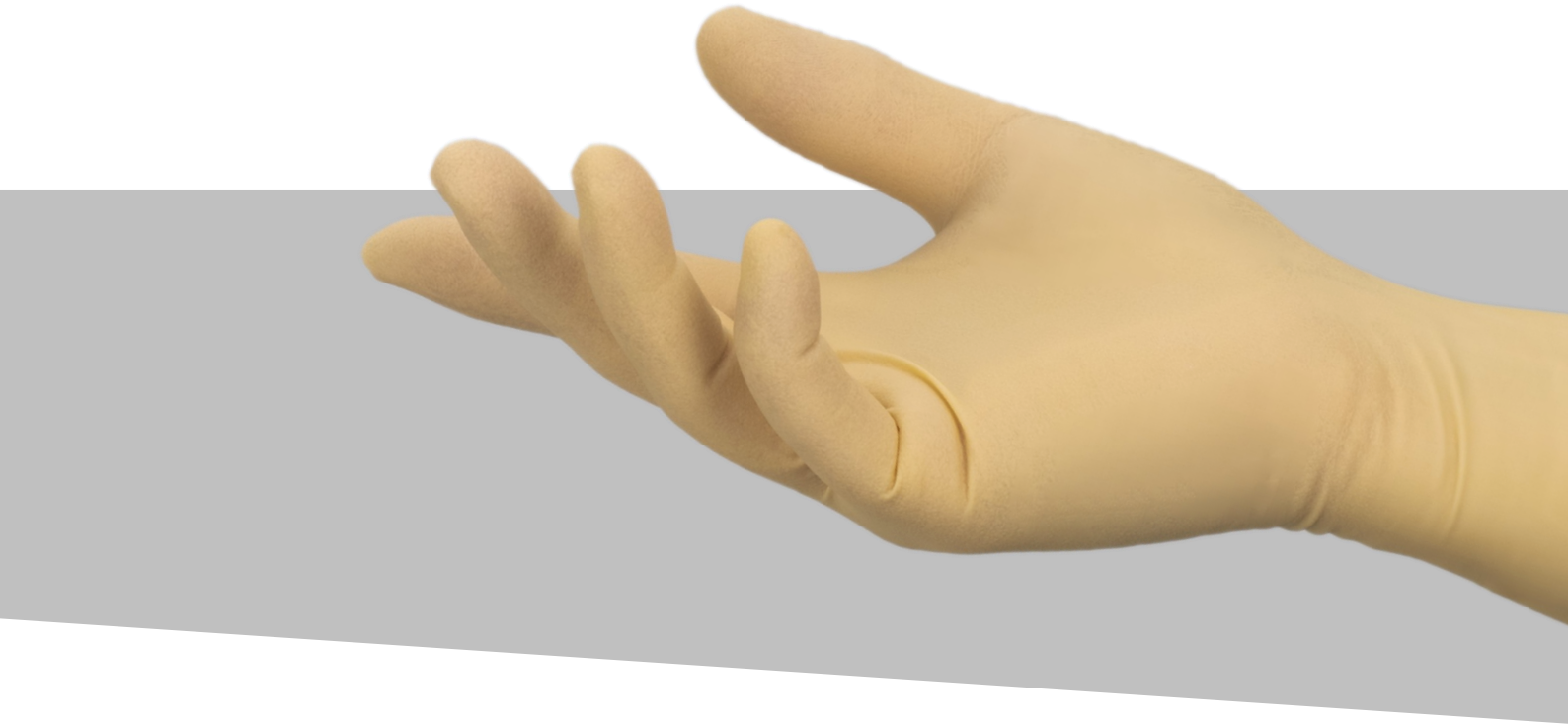
A REVOLUTION IN GLOVE TECHNOLOGY

DI+

HIGH CONTAMINATION CONTROL

TECHNICAL INFORMATION

SHIELDskin XTREME™
Bright Latex 300 DI+



PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425

MDD Medical Device Class I DIRECTIVE 93/42/EEC

CE 0598

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 2 VIRUS

LATEX

⇒ Powder-free triple DI washed ambidextrous standard length (300 mm / 11.8") non-sterile natural rubber latex cleanroom gloves.

⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.

⇒ Medical Device Class 1 (MDD) according to the Directive 93/42/EEC.

⇒ Fully compliant to the latest PPE Protective gloves EU norms against chemicals, micro-organisms and viruses.

DESCRIPTION	
FORMULATION	Natural rubber latex (*Hevea Brasiliensis*).
DESIGN	Natural colour, ambidextrous, beaded cuff, fully textured.
PACKAGING	100 gloves per PE bag - 10 bags per polybag - 1 polybag per carton.

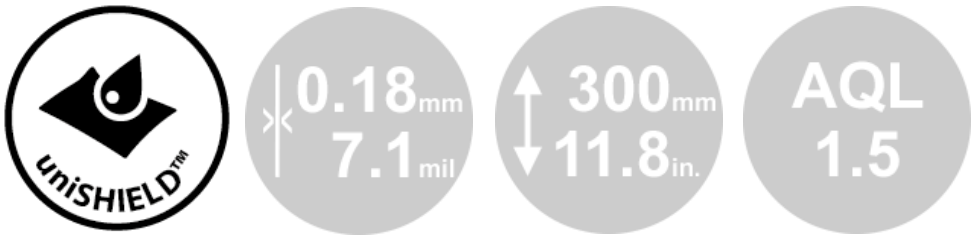
SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
CODES	69 5651	69 5652	69 5653	69 5654	69 5655	69 5656

STANDARDS	
CE REGISTRATION	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. MDD Class 1 - Directive 93/42/EEC.
EU PPE NORMS	EN 420:2003+A1:2009, ISO 374-1:2016+A1:2018, EN 374-2:2014, ISO 374-4:2013, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDD NORMS	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.
USA STANDARDS	ASTM D3767-03 (2014), ASTM D573-04 (2015), ASTM D412-16, ASTM D5712-15 and IEST-RP-CC005.4 (2013).
OTHER STANDARDS	ISO 10993-10:2010.

QUALITY	
QUALITY ASSURANCE	Production management in accordance with ISO 9001:2015 and ISO 13485:2016.
TECHNOLOGY	uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection. Compatible with clean processing environments due to paperless packaging and multiple post leaching of gloves (triple washed in deionised water).

DOCUMENTATION	
DECLARATION OF CONFORMITY	These documents can be freely downloaded from the product page on our website: www.shieldscientific.com. For an easy access, scan the QR code.
EU TYPE EXAMINATION CERTIFICATE	
PRODUCT INSERT	
CERTIFICATE OF CONFORMANCE	To access CoC, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative.

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.20	7.9	ASTM D3767-03 (2014)
⇒ Palm	0.18	7.1	
⇒ Cuff	0.10	3.9	

[1] *Thickness (+/- 0.03 mm)*

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 300 mm / 11.8"	305 mm / 12"	EN 420:2003+A1:2009

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 9.0N	18 Mpa	≥ 700%	12.0N	EN 455-2:2015 ASTM D573-04 (2015) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 Mpa	≥ 500%	11.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 1.5[2]- Level 2	EN 374-2:2014 EN 455-1:2000

[2] *AQL as defined per ISO 2859-1:1999 for sampling by attributes.*

RISKS	Description	Norm
MICRO-ORGANISMS	1000 ml water test. Performance level 2, AQL < 1.5 (inspection level G1).	EN 374-2:2014
VIRUSES	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
CHEMICALS	Performance: Type B (KPT). Permeation: Extensively tested. Online chemical resistance guide on www.shieldscientific.com. Degradation: Tested for determination of resistance to degradation by chemicals.	ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 EN 374-4:2013

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm² ≥ 0.5µm	<1 200 particles	1 000 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm²)	Typical value (µg/cm²)	Test method
Ammonium (NH_4)	0.050	0.015	IEST-RP-CC005.4
Bromide (Br)	0.030	<0.008	
Calcium (Ca)	0.100	0.080	
Chloride (Cl)	0.750	0.370	
Fluoride (F)	0.010	<0.008	
Magnesium (Mg)	0.010	<0.008	
Nitrate (NO_3)	0.400	0.250	
Nitrite (NO_2)	0.050	<0.008	
Phosphate (PO_4)	0.050	<0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.020	
Sulphate (SO_4)	0.100	0.035	

EXTRA TESTS	Description	Test method
NVR	Maximum 30 mg/g.	IEST-RP-CC005.4
FTIR	Non-detectable levels of silicone, amide and DOP.	IEST-RP-CC005.4

ALLERGIES	
BIO-COMPATIBILITY	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
ACCELERATORS	Free of Thiurams and Thiazoles. These chemicals accelerators are excluded from the manufacturing process.
CHEMICAL ALLERGENS	Non-detectable levels using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
LATEX PROTEIN	≤ 50 µg/g as per Modified Lowry Method (EN 455-3:2015/ASTM D5712-15). Typical: ≤ 30 µg/g as per Modified Lowry Method.

SHIELD Scientific
compliance comfort protection

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