SHIELDskin XTREME™

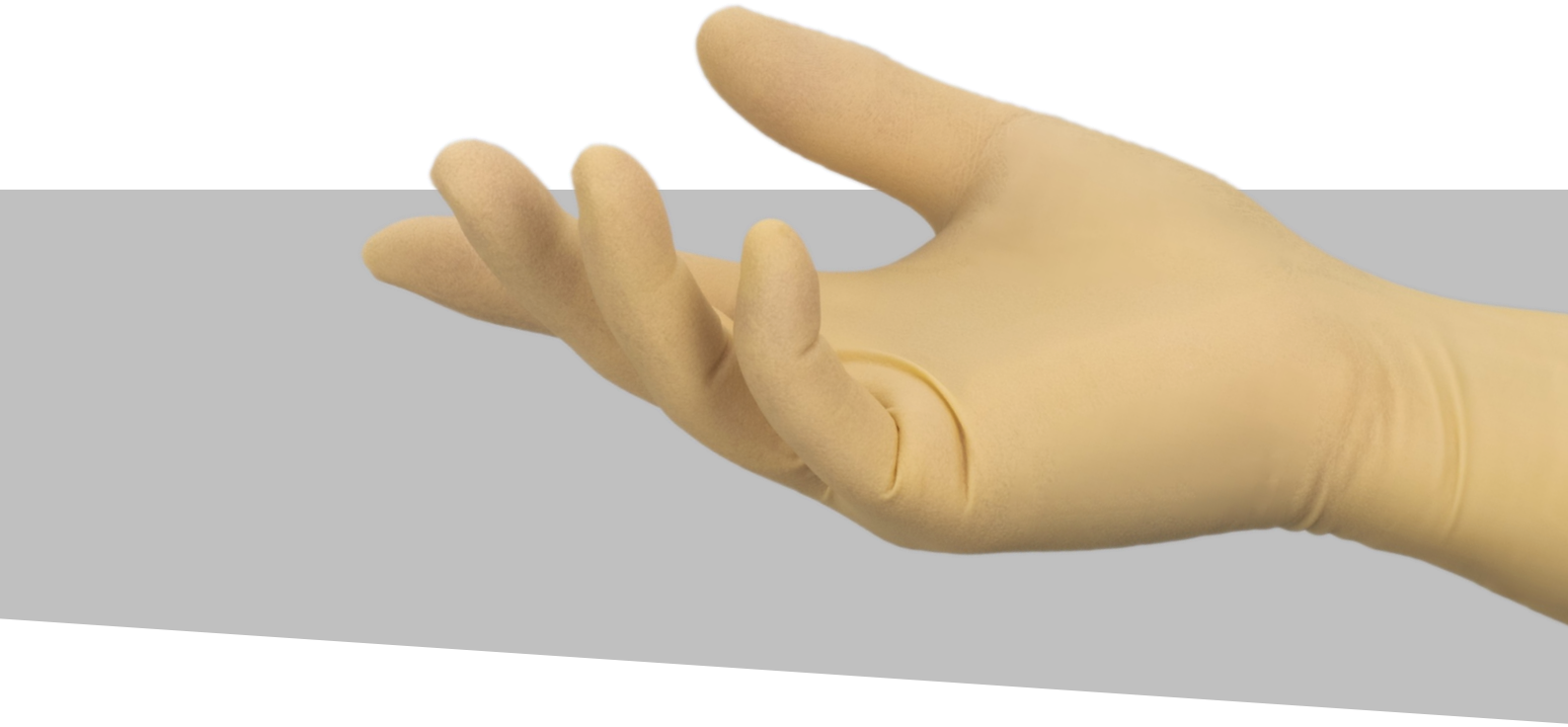
A REVOLUTION IN GLOVE TECHNOLOGY

STERILE

BIO
CONTAMINATION
CONTROL

TECHNICAL INFORMATION

SHIELDskin XTREME™
Sterile Latex 300 DI



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

CE 0598

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 3 VIRUS

LATEX

⇒ Powder-free single DI washed hand-specific standard length (300 mm / 11.8") sterile natural rubber latex cleanroom gloves.

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

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

DESCRIPTION	
FORMULATION	Natural rubber latex (*Hevea brasiliensis*).
DESIGN	Natural colour, hand-specific, beaded cuff, textured palm and fingers.
PACKAGING	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 10 poly bags per PE bag per carton.

SIZES	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9	10
CODES	69 5551	69 5552	69 5553	69 5554	69 5555	69 5556	69 5557	69 5558	69 5559

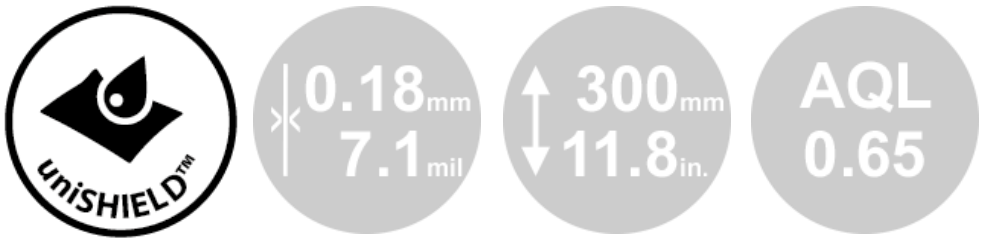
STANDARDS	
CE REGISTRATION	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND.
EU PPE NORMS	EN 420:2003+A1:2009, ISO 374-1:2016+A1:2018, EN 374-2:2014, ISO 374-4:2013, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDD NORMS[1]	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 11137-2:2015, ISO 10993-10:2010.

[1] *With reference to Council Directive 93/42/EEC for Medical Devices*

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 sterile processing environments due to paperless packaging and multiple post leaching of gloves (single 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 and CoI, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative.
CERTIFICATE OF IRRADIATION	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[2]	mil	Norm
⇒ Finger	0.20	7.9	ASTM D3767-03 (2014)
⇒ Palm	0.18	7.1	
⇒ Cuff	0.12	4.7	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 290 mm / 11.4"	300 mm / 11.8"	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%	14.0N	EN 455-2:2015 ASTM D573-04 (2015) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 Mpa	≥ 500%	12.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65[3]- Level 3	EN 374-2:2014

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

RISKS	Description	Norm
MICRO-ORGANISMS	1000 ml water test. Performance level 3, AQL < 0.65 (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	<3 000 particles (spec.)	1 100 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm²)	Typical value (µg/cm²)	Test method
Ammonium (NH_4)	0.100	0.030	IEST-RP-CC005.4
Bromide (Br)	0.030	<0.008	
Calcium (Ca)	0.500	0.250	
Chloride (Cl)	0.750	0.380	
Fluoride (F)	0.010	<0.008	
Magnesium (Mg)	0.010	<0.008	
Nitrate (NO_3)	0.400	0.150	
Nitrite (NO_2)	0.050	<0.008	
Phosphate (PO_4)	0.050	<0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.011	
Sulphate (SO_4)	0.100	0.015	

EXTRA TESTS	Description	Test method
STERILITY	Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6} (ISO 11137-2:2015).	
ENDOTOXINS	Low Endotoxin content at < 20 EU/pair demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.	EN 455-3:2015
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 Thiazoles and Thiurams. These chemical 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

Dr. Willem Dreeslaan 1 ◦ 6721 ND Bennekom ◦ The Netherlands
Phone +31 (0)317 700 202 ◦ Fax +31 (0)318 503 742
E-mail: Info@shieldscientific.com

WWW.SHIELDSCIENTIFIC.COM

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