



# SHIELDskin XTREME™

A REVOLUTION IN GLOVE TECHNOLOGY

DI++

EXTREME  
CONTAMINATION  
CONTROL

## TECHNICAL INFORMATION

SHIELDskin XTREME™  
White Nitrile 300 DI++



- ⇒ Powder-free multiple DI washed ambidextrous standard length (305 mm / 12") non-sterile nitrile 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	Nitrile synthetic rubber (acrylonitrile butadiene).
DESIGN	White, ambidextrous, beaded cuff, textured fingertips.
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 8851	69 8852	69 8853	69 8854	69 8855	69 8856

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 (2016) and IEST-RP-CC005.4 (2013).
OTHER STANDARDS	EN 1149-1/2/3 & 5, 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. Synthetic soft polymer based on Skin Nitrile™ technology. Compatible with clean processing environments due to paperless packaging and multiple post leaching of gloves (multi washed in deionised water).

DOCUMENTATION	
DECLARATION OF CONFORMITY	These documents can be freely downloaded from the product page on our website: <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> . 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 <a href="mailto:info@shieldscientific.com">info@shieldscientific.com</a> or call your SHIELD Scientific representative.



# PHYSICAL PROPERTIES



NOMINAL THICKNESS		mm <sup>1</sup>	mil	Norm
⇒	Finger	0.19	7.5	ASTM D3767-03 (2014)
⇒	Palm	0.14	5.5	
⇒	Cuff	0.11	4.3	

<sup>1</sup> Thickness (+/- 0.03 mm)

LENGTH		Minimum	Typical	Norm
⇒	From middle finger tip to edge of cuff	≥ 295 mm / 11.6"	305 mm / 12.0"	EN 420:2003+A1:2009

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm	
	⇒	Before aging	≥ 6.0N	14 Mpa		≥ 500%
⇒	After aging	≥ 6.0N	14 Mpa	≥ 400%	10.0N	

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

<sup>2</sup> 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	<u>Performance</u> : Type B (KPT). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> . <u>Degradation</u> : 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/cm <sup>2</sup> ≥ 0.5µm	<850 particles	600 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm <sup>2</sup> )	Typical value (µg/cm <sup>2</sup> )	Test method
Ammonium (NH <sub>4</sub> )	0.020	0.009	IEST-RP-CC005.4
Bromide (Br)	0.020	<0.008	
Calcium (Ca)	0.200	0.120	
Chloride (Cl)	0.100	0.070	
Fluoride (F)	0.010	<0.008	
Magnesium (Mg)	0.010	<0.008	
Nitrate (NO <sub>3</sub> )	0.100	0.070	
Nitrite (NO <sub>2</sub> )	0.020	<0.008	
Phosphate (PO <sub>4</sub> )	0.020	<0.008	
Potassium (K)	0.030	0.013	
Sodium (Na)	0.020	0.011	
Sulphate (SO <sub>4</sub> )	0.020	<0.008	
Zinc (Zn)	0.050	0.030	

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
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5

ALLERGIES	
BIO-COMPATIBILITY	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
ACCELERATORS	Accelerator-free to minimize the risk of allergic contact dermatitis (also known as Type IV, delayed hypersensitivity or chemical allergy).
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	Latex-free.



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