



SHIELDskin XTREME™

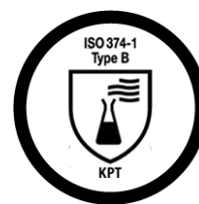
A REVOLUTION IN GLOVE TECHNOLOGY

STERILE

BIO
CONTAMINATION
CONTROL

TECHNICAL INFORMATION

SHIELDskin XTREME™
Sterile White Nitrile 400 DI+



STERILEBIO
CONTAMINATION
CONTROL**DI+**HIGH
CONTAMINATION
CONTROL

- ⇒ Powder-free triple DI washed hand-specific extra length (400 mm / 15.7") sterile nitrile 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	Nitrile synthetic rubber (acrylonitrile butadiene).
DESIGN	White, hand-specific, beaded cuff, textured palm and fingers.
PACKAGING	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 8 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 8771	69 8772	69 8773	69 8774	69 8775	69 8776	69 8777	69 8778	69 8779

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 D6978-05 (2013) and IEST-RP-CC005.4 (2013).
OTHER STANDARDS	ISO 11137-2:2015, ISO 10993-10:2010.

¹With 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. Synthetic soft polymer based on Skin Nitrile™ technology. Compatible with sterile 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 .	
EU TYPE EXAMINATION CERTIFICATE		
PRODUCT INSERT		
CERTIFICATE OF CONFORMANCE	To access CoC and Col, 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	0.18	7.1	ASTM D3767-03 (2014)
⇒	Palm	0.15	5.9	
⇒	Cuff	0.10	3.9	

² Thickness (+/- 0.03 mm)

LENGTH		Minimum	Typical	Norm
⇒	From middle finger tip to edge of cuff	≥ 400 mm / 15.7"	405 mm / 15.9"	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%	8.0N	

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 ⁴	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
CHEMICALS ⁴	<u>Performance</u> : Type B (KPT). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on www.shieldscientific.com . <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
CYTOTOXIC	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

⁴ For PPER compliance, > 40 cm gloves are palm and cuff tested for permeation, degradation and viral penetration.

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm ² ≥ 0.5µm	<1 200 particles	1 000 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm ²)	Typical value (µg/cm ²)	Test method
Ammonium (NH ₄)	0.050	0.018	IEST-RP-CC005.4
Bromide (Br)	0.030	<0.008	
Calcium (Ca)	0.350	0.250	
Chloride (Cl)	0.200	0.110	
Fluoride (F)	0.010	<0.008	
Magnesium (Mg)	0.010	<0.008	
Nitrate (NO ₃)	0.200	0.050	
Nitrite (NO ₂)	0.050	<0.008	
Phosphate (PO ₄)	0.050	<0.008	
Potassium (K)	0.050	0.023	
Sodium (Na)	0.050	0.012	
Sulphate (SO ₄)	0.050	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	Latex-free.



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