



SHIELDskin XTREME™

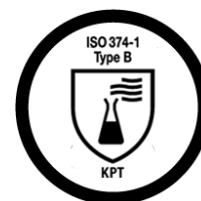
A REVOLUTION IN GLOVE TECHNOLOGY

STERILE

BIO
CONTAMINATION
CONTROL

TECHNICAL INFORMATION

SHIELDskin XTREME™
Sterile ORANGE NITRILE™ 300 DI



- ⇒ Powder-free single DI washed hand-specific standard length (300 mm / 11.8") sterile nitrile/neoprene 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 and neoprene synthetic rubber (acrylonitrile butadiene and polychloroprene).
DESIGN	Orange, 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 6551	69 6552	69 6553	69 6554	69 6555	69 6556	69 6557	69 6558	69 6559

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 (2019) and IEST-RP-CC005.4 (2013).
OTHER STANDARDS	ISO 11137-2:2015, ISO10993-10:2010.

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 with a blend of polychloroprene. 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 .
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	0.15	5.9	ASTM D3767-03 (2014)
⇒	Palm	0.14	5.5	
⇒	Cuff	0.09	3.5	

² 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	≥ 6.0N	14 Mpa	≥ 500%	12.0N	EN 455-2:2015 ASTM D573-04 (2015) & ASTM D412-16
⇒	After aging	≥ 6.0N	14 Mpa	≥ 400%	11.0N	

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	<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)

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm ² ≥ 0.5µm	<3 000 (spec.)	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	0.015	IEST-RP-CC005.4
Bromide (Br)	0.030	<0.008	
Calcium (Ca)	0.500	0.300	
Chloride (Cl)	0.400	0.100	
Fluoride (F)	0.010	<0.008	
Magnesium (Mg)	0.010	<0.008	
Nitrate (NO ₃)	0.200	0.090	
Nitrite (NO ₂)	0.050	<0.008	
Phosphate (PO ₄)	0.050	<0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.008	
Sulphate (SO ₄)	0.050	0.008	

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
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.



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