duoSHIELD™

FOR HANDS THAT MAKE A DIFFERENCE

BLUE

DUAL
RISK

TECHNICAL INFORMATION

duoSHIELD™
PFT Nitrile 240

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 3 VIRUS

⇒ Powder-free ambidextrous standard length (240 mm / 9.4") non-sterile nitrile exam 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 EU PPE norms relating to protective gloves against chemicals, micro-organisms and viruses.

DESCRIPTION	
FORMULATION	Nitrile synthetic rubber (acrylonitrile butadiene).
DESIGN	White, ambidextrous, beaded cuff, textured fingertips.
PACKAGING	200 gloves per dispenser - 10 dispensers per case.

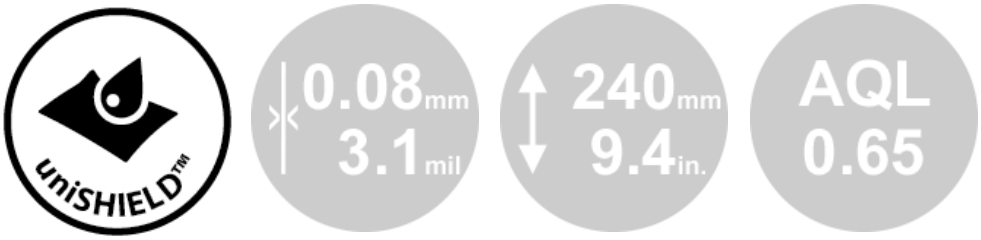
SIZES	6/XS	7/S	8/M	9/L	10/XL
CODES	65 8121	65 8122	65 8123	65 8124	65 8125

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, EN 421:2010, 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.
OTHER STANDARDS	ISO 21171:2006.

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.

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	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.10	3.9	ASTM D3767-03 (2014)
⇒ Palm	0.08	3.1	
⇒ Cuff	0.07	2.8	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	240 mm / 9.4"		EN 420:2003+A1:2009 EN 455-2:2015

STRENGTH PROPERTIES	Force at break (spec.)	Force at break (typical)	Ultimate elongation	Norm
⇒ Before aging	≥ 6.0N	7.0N	≥ 500%	EN 455-2:2015
⇒ After aging	≥ 6.0N	8.0N	≥ 400%	ASTM D573-04 (2015) & ASTM D412-16

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65[2] - Level 3	EN 455-1:2000 EN 374-2:2014

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

PROTECTION PROPERTIES

RISKS	Description	Norm
MICRO-ORGANISMS	1000 ml water test. Performance level 3, AQL < 0.65 (inspection level G1).	EN 455-1:2000 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
RADIOACTIVITY	Protection from radioactive contamination.	EN 421:2010
FIT FOR SPECIAL PURPOSE	Size and length: Sizes 10 (XL and 9 (L) gloves are shorter in length than that required by EN 420:2003+A1:2009. These gloves are intended for use in light-duty manufacturing and industrial applications where the demand for the advantages of a shorter glove outweighs the need for additional length.	EN 420:2003 +A1:2009

ALLERGIES	
BIO-COMPATIBILITY	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
ACCELERATORS	Free of Thiazoles. This chemical accelerator is excluded from the manufacturing process.
RESIDUAL POWDER	Powder-free to minimize the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006).
LATEX PROTEIN	Latex-free.

SHIELD Scientific
compliance comfort protection

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