duoSHIELD™
FOR HANDS THAT MAKE A DIFFERENCE

BLUE
DUAL RISK

duoSHIELD™
PFT Nitrile 290

DOMINIQUE DUTSCHER SAS

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

MDR
Medical Device
Class I
REGULATION
(EU)2017/745

CE
2797

UK
CA
0086

ISO 374-1/Type B
KPT

ISO 374-5:2016
VIRUS

Dual risk

⇒ Powder-free ambidextrous extra length (290 mm / 11.4") non-sterile nitrile exam gloves.

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

⇒ Medical Device Class 1 (MDR) according to the Regulation (EU) 2017/745.

⇒ 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	Blue, ambidextrous, beaded cuff, textured fingertips.
Packaging	100 gloves per dispenser - 10 dispensers per carton = 1000 gloves.

SIZES	6/XS	7/S	8/M	9/L	10/XL
Codes	65 8141	65 8142	65 8143	65 8144	65 8145

STANDARDS	
CE/UKCA registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. CE Notified Body No 2797: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, Unit 4.2, 1066 EP Amsterdam, The Netherlands. UKCA Notified Body No 0086: BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom. MDR Class 1 - Regulation (EU) 2017/745.
EU PPE norms	ISO 21420:2020+A1:2022, EN 421:2010, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDR norms	EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.
USA standards	ASTM D3767-03 (2020), ASTM D573-04 (2019), ASTM D412-16, ASTM D6978-05 (2019).
Other standards	ISO 21171:2006, ISO 10993-10:2021.

QUALITY	
Quality assurance	Production management in accordance with ISO 9001:2015 and ISO 13485:2016. Environmental management systems in accordance with ISO 14001:2015.
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 easy access, scan the QR code.
EU type examination certificate	
User's instructions	

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PHYSICAL PROPERTIES

NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.10	3.9	ASTM D3767-03 (2020)
⇒ 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	≥ 290 mm / 11.4"	290 mm / 11.4"	ISO 21420:2020+A1:2022 EN 455-2:2015

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	10.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	8.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65[2] G1 - Level 3	EN 455-1:2020 ISO 374-2:2019

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

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PROTECTION PROPERTIES

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 3, AQL < 0.65 (inspection level G1).	EN 455-1:2020 ISO 374-2:2019
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: 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 ISO 374-4:2019
Radioactivity	Protection from radioactive contamination.	EN 421:2010
Cytotoxic	Tested for permeation to potentially hazardous cancer chemo-therapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

ALLERGIES	
Bio-compatibility	Demonstrated by skin irritation and sensitisation tests in accordance with ISO 10993-10:2021.
Accelerators	Free of Thiurams and Thiazoles. These chemicals accelerators are excluded from the manufacturing process.
Residual powder	Powder-free to minimise 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.

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