

EU DECLARATION OF CONFORMITY

FOR PERSONAL PROTECTIVE EQUIPMENT

Originator: J.F ROBLES

Revision: 010

Revision date: 20.07.2020 Validity date: 31.01.2025

Sizes 5.5 6 6.5 7 7.5 8 8.5 9 10

PRODUCT	SHIELDskin XTREME™	SHIELD Scientific codes	ç
	Sterile White Nitrile 330 DI+	69 8761	
		69 8762	
DESCRIPTION	Powder-free Extra DI washed Pair-packed Hand-specific 33cm Cleanroom Gloves Personal Protective Equipment (PPE) Category III (Complex Design)	69 8763	
		69 8764	
		69 8765	
		69 8766	
		69 8767	
		69 8768	
		69 8769	

The manufacturer established in the Union:

SHIELD Scientific B.V.

Dr Willem Dreeslaan 1 – 6721 ND BENNEKOM – THE NETHERLANDS

declares under his/her sole responsibility that the PPE (product codes as mentioned above) described hereafter:

SHIELDskin XTREME[™] Sterile White Nitrile 330 DI+

is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards ISO 374-1:2016 (as a Type B glove against reagents: J, K & P), ISO 374-2:2014 (performance level 3, including protection against viruses), EN 16523-1:2015 + A1:2018, ISO 374-4:2013, ISO 374-5:2016 and ISO 21420:2020. This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. FI20/965207 issued by the Notified Body:

SGS FIMKO OY (Notified Body No: 0598) Takomotie 8, FI-00380 Helsinki, Finland

This device is subject to the procedure set out in Article VIII (Module D) of the Regulation under the surveillance of the Notified Body:

TÜV SÜD Product Service GmbH (Notified Body No: 0123), Ridlerstrasse 65, 80339 MÜNCHEN, Germany

Signed for and behalf of SHIELD Scientific B.V

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Date: 20th July 2020 Place: Bennekom Validity of this declaration: 20th July 2020 until 31st January 2025

J.F ROBLES General Manager