

## **EU DECLARATION OF CONFORMITY**

FOR PERSONAL PROTECTIVE EQUIPMENT

Originator: J.F ROBLES Revision: 008 Revision date: 20.07.2020 Validity date: 31.01.2025

PRODUCT	SHIELDskin XTREME™ Sterile ORANGE NITRILE™ 300 DI
DESCRIPTION	Powder-free DI washed Pair-packed Hand- specific 30cm Cleanroom Gloves
CLASSIFICATION	Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
69 6551	5.5
69 6552	6
69 6553	6.5
69 6554	7
69 6555	7.5
69 6556	8
69 6557	8.5
69 6558	9
69 6559	10

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 ORANGE NITRILE™ 300 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: K, P & T), 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.* FI2O/965206 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:

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

Signed for and behalf of SHIELD Scientific B.V

J.F ROBLES -

General Manager

Date: 20<sup>th</sup> July 2020 Place: Bennekom

Validity of this declaration: 20<sup>th</sup> July 2020 until 31<sup>st</sup> January 2025