



EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPMENT

Originator: J.F ROBLES

Revision: 010

Revision date: 13.07.2020

Validity date: 27.02.2025

PRODUCT	SHIELDskin XTREME™ ORANGE NITRILE™ 300 DI
DESCRIPTION	Powder-free DI washed Ambidextrous Non-Sterile 30cm Cleanroom Nitrile Gloves
CLASSIFICATION	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
69 6451	6/XS
69 6452	7/S
69 6453	8/M
69 6454	9/L
69 6455	10/XL
69 6456	11/XXL

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 Medical Device and PPE (product codes as mentioned above) described hereafter:

SHIELDskin XTREME™ ORANGE NITRILE™ 300 DI

is in conformity with the provisions of the Medical Device Regulation (EU) 2017/745 and with the national standards transposing harmonized standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. It is self-certified as a Medical Device Class 1.

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 & T), ISO 374-2:2019 (performance level 3, including protection against viruses), EN 16523-1:2015 + A1:2018, ISO 374-4:2019, 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. FI18/962116 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: 13th July 2020

Place: Bennekom

Validity of this declaration: 13th July 2020 until 27th February 2025