EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPMENT

Originator: J.F ROBLES	**Revision:** 012	**Revision date:** 10.03.2022	**Validity date:** 24.02.2025

PRODUCT	SHIELDskin XTREME™ White Nitrile 300 DI
DESCRIPTION	Powder-free DI washed or Multi-Chlorinated Ambidextrous Non-Sterile 30cm Cleanroom Nitrile Gloves
CLASSIFICATION	Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
69 8451	6/XS
69 8452	7/S
69 8453	8/M
69 8454	9/L
69 8455	10/XL
69 8456	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 PPE (product codes as mentioned above) described hereafter:

SHIELDskin XTREME™ White 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 374-2:2019 (performance level 2, 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. FI20/965422* 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

Date: 10th March 2022
Place: Bennekom
Validity of this declaration: 29th April 2021 until 24th February

J.F ROBLES
General Manager