

## **EU DECLARATION OF CONFORMITY**

FOR PERSONAL PROTECTIVE EQUIPMENT

**Originator: J.F ROBLES** 

Revision: 013

Revision date: 20.07.2020 Validity date: 27.02.2025

PRODUCT	SHIELDskin <sup>™</sup> ORANGE NITRILE <sup>™</sup> 300 Sterile
DESCRIPTION	Powder-free Extra Length Ambidextrous Sterile 30 cm Nitrile Gloves
CLASSIFICATION	Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
67 6351	6/XS
67 6352	7/S
67 6353	8/M
67 6354	9/L
67 6355	10/XL
67 6356	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<sup>™</sup> ORANGE NITRILE<sup>™</sup> 300 Sterile

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 374-2:2014 (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. FI18/962117 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

Date: 20<sup>th</sup> July 2020 Place: Bennekom Validity of this declaration: 20<sup>th</sup> July 2020 until 27<sup>th</sup> February 2025

J.F ROBLES **General Manager**