EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPMENT

Originator: J.F ROBLES	**Revision:** 010	**Revision date:** 13.07.2020	**Validity date:** 02.06.2025

PRODUCT	duoSHIELD™ PFT Latex 240
DESCRIPTION	Powder-free Ambidextrous Non-Sterile 24 cm Textured Natural Rubber Gloves
CLASSIFICATION	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
65 4121	6/XS
65 4122	7/S
65 4123	8/M
65 4124	9/L
65 4125	10/XL

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:

duoSHIELD™ PFT Latex 240

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: 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 ISI 21420:2020. This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. FI20/965914 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 02nd June 2025