



EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPMENT

Originator: J.F ROBLES

Revision: 003

Revision date: 29.04.2021

Validity date: 28.01.2024

PRODUCT	SMARTLine™ Powder-free blue nitrile gloves, 240
DESCRIPTION	Powder-free Short Length Ambidextrous Non-Sterile 24 cm Nitrile Gloves
CLASSIFICATION	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
10 621	6/XS
10 622	7/S
10 623	8/M
10 624	9/L
10 625	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:

SMARTLine™ Powder-free blue nitrile gloves, 240

is in conformity with the provisions of the Medical Device Regulation (EU) 2017/745 and with the national standards transposing harmonized standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. It is self-certified as a Medical Device Class 1. Single Registration Number (SRN) NL-MF-000001691 and Basic UDI-DI 8719632071062XZP refer.

is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards ISO 374-1:2016 (as a Type C glove against reagents: K), 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. 2777/11793-01/E00-00 issued by the Notified Body:

SATRA Technology Europe LTD (Notified Body No: 2777)
Bracetown Business Park, D15YN2P Clonee, Republic of Ireland

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: 29th April 2021
Place: Bennekom
Validity of this declaration: 29th April 2021 until 28th January 2024