

EC Declaration of Conformity for Medical Devices and Personal **Protective Equipment**

Revision:

27.11.17

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Revision Date: Originator: J.F. Robles

Product: duoSHIELD™ PFT Nitrile 240 Powder Free Ambidextrous Non-Sterile 24 cm

Nitrile Gloves with Textured Fingertips

Product Codes: SHIELD Scientific codes Size

65 8121 6/XS 65 8122 7/S 65 8123 8/M 65 8124 9/L 65 8125 10/XL

Classification: Medical Device Class 1 / Personal Protective Equipment (PPE) Category III

(Complex Design)

The manufacturer established in the Community:

SHIELD Scientific B.V., Dr Willem Dreeslaan 1, 6721 ND BENNEKOM, The Netherlands

declares that the new Medical Device and PPE (Product Codes as mentioned above) described hereafter:

duoSHIELD™ PFT Nitrile 240

is in conformity with the provisions of Council Directive 93/42/EEC 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 selfcertified as a Medical Device Class 1.

is in conformity with the provisions of Council Directive 89/686/EEC and with the harmonized standards EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015 (supersedes EN 374-3: 2003), EN 374-4:2013, EN ISO 374-5:2016 and EN 420:2003 + A1:2009. This device is identical to the PPE, which is the subject of EC certificate of conformity no. GB17/873537 issued by the Notified Body:

> SGS UK Ltd (Notified Body No: 0120), Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA, **United Kingdom**

This device is subject to the procedure set out in Article 11 point B of Directive 89/686/EEC under the supervision of the Notified Body:

> SGS UK Ltd (Notified Body No: 0120), Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA, **United Kingdom**

Done at Bennekom on 27th November 2017.

J.F ROBLES General Manager



Validity of this Declaration: 27th November 2017 until 27th November 2022.

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