SHIELD Scientific compliance comfort protection	EC Declaration of Conformity for Medical Devices and Personal Protective Equipment	Revision: 01 Revision Date: 27.11.17 Originator: J.F. Robles

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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 self-certified 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.