



SHIELD Scientific
compliance comfort protection

EU DECLARATION OF CONFORMITY

Originator: J.F ROBLES

Revision N°: 005

Revision date: 28.04.2021

Validity date: 12/05/2025

Product	duoSHIELD™ PFT Nitrile 290
Description	Powder-free ambidextrous non-sterile 29 cm nitrile gloves with textured fingertips
Classification	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

Product codes	Sizes
65 8141	6/XS
65 8142	7/S
65 8143	8/M
65 8144	9/L
65 8145	10/XL
N/A	N/A
N/A	N/A
N/A	N/A
N/A	N/A

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:

duoSHIELD™

PFT Nitrile 290

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+A1:2022, EN 455-2:2015, EN 455-3:2015 & EN 455-4:2009 . It is selfcertified as a Medical Device Class 1. Single Registration Number (SRN) NL-MF-000001691 and Basic UDI-DI 87196320765814XX6 refer.

is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards EN ISO 374-1:2016 + A1:2018 (as a Type B glove against reagents: K, P & T) EN ISO 374-5:2016 & EN 420:2003+A1:2009 as well as test method ISO 374-2:2019 (performance level 3), including protection against viruses (ISO 16604:2004), EN 16523-1:2015 + A1:2018 & EN ISO 374-4:2019. . This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. F119/964986 issue 2 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 Annex VIII (ModuleD) of the Regulation under the surveillance of the Notified Body:

SGS FIMKO OY (Notified Body No: 0598) Takomotie 8, FI-00380 Helsinki, Finland

J.F ROBLES
General Manager
Date: 28.04.2021
Place: Bennekom

 **SHIELD Scientific**
compliance comfort protection
