



Originator: J.F. Robles

Revision N°: 017

Revision date: 19.03.2025

Validity date: 17/12/2029

Product	SHIELDskin™ ORANGE NITRILE™ 260
Description	Powder-free extra length ambidextrous non-sterile 26 cm nitrile gloves
Classification	Medical Device Class I / Personal Protective Equipment (PPE) Category III (Complex Design)

Product codes	Sizes
67 6231	6/XS
67 6232	7/S
67 6233	8/M
67 6234	9/L
67 6235	10/XL
N/A	N/A

The manufacturer established in the Union:

SHIELD Scientific B.V.

(Costerweg 1-B – 6702 AA Wageningen – The Netherlands)

declares under his/her sole responsibility that the PPE (product codes as mentioned above) described hereafter:

SHIELDskin™

ORANGE NITRILE™ 260

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 455-2:2024, EN 455-3:2023 & EN 455-4:2009 . It is selfcertified as a Medical Device Class I. Single Registration Number (SRN) NL-MF-000001691 and Basic UDI-DI 87196320767623XXG 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: J, K, P & T) EN ISO 374-5:2016 & EN ISO 21420:2020 as well as test method EN 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. CE 811858 issued by the Notified Body:

BSI Group The Netherlands B.V. (Notified Body No: 2797) Say Building, John M. Keynesplein 9, Unit 4.2, 1066 EP Amsterdam, The Netherlands

This device is subject to the procedure set out in Annex VIII (ModuleC2) of the Regulation under the surveillance of the Notified Body:

BSI Group The Netherlands B.V. (Notified Body No: 2797) Say Building, John M. Keynesplein 9, Unit 4.2, 1066 EP Amsterdam, The Netherlands

J.F. Robles
Managing Director
Date: 19.03.2025
Place: Wageningen

