



Originator: J.F. Robles

Revision N°: 001

Revision date: 09.09.2025

Validity date: 17.12.2029

Product	SMARTLine™ NEO NITRILE™ 290
Description	Powder-free extra length ambidextrous non-sterile 29 cm multi-polymer gloves
Classification	Medical Device Class I / Personal Protective Equipment (PPE) Category III (Complex Design)

Product codes	Sizes
10 831	6/XS
10 832	7/S
10 833	8/M
10 834	9/L
10 835	10/XL
10 836	11/XXL
N/A	N/A
N/A	N/A
N/A	N/A

The manufacturer established in the The Netherlands:

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:

SMARTLine™

NEO NITRILE™ 290

is in conformity with the provisions of the UK Medical Device Regulation 2002 (as amended) and with the designated standards EN 455-1:2020 + A2:2024, EN 455-2:2024, EN 455-3:2023 & EN 455-4:2009 . It is self-certified as a Medical Device Class I and is under the supervision of the UK Responsible Person, UKCApartner4U Ltd (7 Campion Way, Bingham, Nottingham, NG13 8TR, UK) N/A . Basic UDI-DI 8719632071083X27 refer.

is in conformity with the provisions of UKCA Regulation 2016/425 (as amended to apply in GB) and with the designated standards EN ISO 374-1:2016 + A1:2018 A A glove against reagents: K,P,T,O,M,S) EN ISO 374-5:2016 & EN ISO 21420:2020+A1:2024 as well as test method EN ISO 374-2:2019 (performance level 2), 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 UKCA Type Examination (Module B) certificate of conformity no. UKCA 811867 formally covered by: or issued by the Notified Body:

BSI Assurance UK Ltd (Approved Body No: 0086)Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom

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

BSI Assurance UK Ltd (Approved Body No: 0086)Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom

J.F. Robles
General Manager
Date: 09.09.2025
Place: Wageningen

