



Originator: J.F. Robles

Revision N°: 001

Revision date: 19.03.2025

Validity date: 16.12.2029

Product	SMARTLine™ Sterile Latex 400 DI
Description	Powder-free DI washed ambidextrous sterile 40 cm natural rubber latex cleanroom gloves
Classification	Personal Protective Equipment (PPE) Category III (Complex Design)

Product codes	Sizes
20 451	6/XS
20 452	7/S
20 453	8/M
20 454	9/L
20 455	10/XL
20 456	11/XXL
N/A	N/A
N/A	N/A
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:

SMARTLine™

Sterile Latex 400 DI

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 ISO 21420:2020 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 EU Type Examination (Module B) certificate of conformity no. CE 811857 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 (Module C2) 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

