



Originator: J.F. Robles

Revision N°: 002

Revision date: 19.03.2025

Validity date: 14.09.2027

<b>Product</b>	ecoSHIELD™ Eco Latex PF 250
<b>Description</b>	Powder-free ambidextrous non-sterile 25 cm smooth natural rubber latex gloves
<b>Classification</b>	Medical Device Class I / Personal Protective Equipment (PPE) Category III (Complex Design)

Product codes	Sizes
62 3131	6/XS
62 3132	7/S
62 3133	8/M
62 3134	9/L
62 3135	10/XL
N/A	N/A
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:

**ecoSHIELD™**

**Eco Latex PF 250**

is in conformity with the provisions of the UK Medical Device Regulation 2002 (as amended) and with the designated standards EN 455-1:2020 + A1:2022, 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 87196320762313XUX 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 B 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 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 UKCA Type Examination (Module B) certificate of conformity no. UKCA 811862 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: 19.03.2025  
Place: Wageningen