



## EU Declaration of Conformity for Medical Devices

**ORIGINAL**

Revision: 01  
Issue Date: 01.05.2020  
Originator: J.F. Robles

<b>Product</b>	Black Nitrile 240 - Powder-Free Ambidextrous Non-Sterile 24cm Nitrile Exam Glove with Textured Fingers
<b>Product Codes</b>	87 2121 (XS/6), 87 2122 (S/7), 87 2123 (M/8), 87 2124 (L/9) & 87 2125 (XL/10)
<b>GMDN</b>	40546 (Glove, patient examination, non-latex)
<b>EU Representative</b>	SHIELD Scientific B.V. ◦ Dr Willem Dreeslaan 1 ◦ 6721 ND BENNEKOM ◦ The Netherlands ◦ Phone +31 (0)317 700 202 ◦ Fax +31 (0)318 503 742
<b>Base Polymer</b>	Acrylonitrile butadiene co-polymer EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009

### This Product contains no Natural Rubber Latex

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 Medical Device (product codes as mentioned above) described hereafter:

CE-Certification of Medical Devices class 1, as per Classification Rules detailed in Annex VIII of Regulation (EU) 2017/745. Here: model Black Nitrile 240 - Powder-Free Ambidextrous Non-Sterile 24cm Nitrile Exam Glove with Textured Fingers, product codes 87 2121 (XS/6), 87 2122 (S/7), 87 2123 (M/8), 87 2124 (L/9) & 87 2125 (XL/10)

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer, SHIELD Scientific B.V. We hereby declare that the above-mentioned device complies with the Regulation (EU) 2017/745 of the European Parliament and of the Council and is in accordance with Annex IV of the Regulation, supported by the Conformity Assessment and adhering to the General safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745.

This declaration is made on the basis of the Quality Assurance Certificate No MY00/51711 of SGS UK and is also based on the existing Technical Documentation as per Annex II of the Regulation (EU) 2017/745. CE marking is carried out as per Annex V of Regulation (EU) 2017/745.

This declaration is valid for the above product in its original, unmodified, unopened and undamaged packaging of the smallest unit.



J.F. Robles  
General Manager

Date: 1<sup>st</sup> May 2020  
Place: Bennekom

Validity of this Declaration: 1<sup>st</sup> May 2020 until 31<sup>st</sup> December 2021

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