



## Declaration of Conformity for Medical Devices

**ORIGINAL**

Revision: 06  
Revision Date: 01.01.18  
Originator: J.F. Robles

### Declaration of Conformity

<b>Product</b>	duoSHIELD™ PFS Latex 240 - Powder-Free Ambidextrous Non-Sterile 24cm Smooth Latex Exam Glove
<b>Product Codes</b>	65 3121 (XS/6), 65 3122 (S/7), 65 3123 (M/8), 65 3124 (L/9), 65 3125 (XL/10)
<b>GMDN</b>	34020 (Glove, patient examination, latex)
<b>EEC 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>	Natural Rubber Latex
<b>Product Standards</b>	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009
<b>Additional Standards</b>	EN 388:1994, EN 374-2:1994 (AQL 1.5 achieved by EN 455-1:2000), EN 374-3:1994 and EN 420:1994 (Product Test Data available on request)

CE-Certification of Medical Devices class 1, as per Annex IX of the Council Directive 93/42/EEC. Here: model duoSHIELD™ Powder-Free Ambidextrous Non-Sterile 24cm Smooth Latex Exam Glove, multilingual, product codes 65 3121 (XS/6), 65 3122 (S/7), 65 3123 (M/8), 65 3124 (L/9) and 65 3125 (XL/10).

We hereby declare that the above mentioned device complies with the European Medical Device Directive 93/42/EEC and is in accordance with Annex VII of the EEC Directive, supported by the Conformity Assessment Procedure and adhering to the essential requirements in accordance with Annex 1 of the European Medical Device Directive 93/42/EEC.

This declaration is made on the basis of the Quality Assurance Certificate No GB00/51447 of SGS UK and is also based on the existing Technical Documentation as per Annex VII paragraph 3 of the European Medical Device Directive 93/42/EEC. CE marking is carried out as per Annex XII of the European Medical Devices Directive 93/42/EEC.

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

Validity of this Declaration: 1<sup>st</sup> January 2018 until 31<sup>st</sup> December 2019

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