Declaration of Conformity

Product	duoSHIELD™ PFH 240 Latex - Powder Free Ambidextrous Non-Sterile 24 cm Textured Latex Exam Gloves
Product Codes	64 4121 (XS/6), 64 4122 (S/7), 64 4123 (M/8), 64 4124 (L/9) & 64 4125 (XL/10)
GMDN	34020 (Glove, patient examination, latex)
EEC Representative	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
Base Polymer	Natural Rubber Latex
Product Standards	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009
Additional Standards	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™ PFH 240 Latex - Powder Free Ambidextrous Non-Sterile 24 cm Textured Latex Exam Gloves, multilingual product codes 64 4121 (XS/6), 64 4122 (S/7), 64 4123 (M/8), 64 4124 (L/9) & 64 4125 (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: 1st January 2018 until 31st December 2019