SHIELD Scientific compliance comfort protection	Declaration of Conformity for Medical Devices	ORIGINAL Revision: 05 Revision Date: 01.01.16 Originator: J.F. Robles

Declaration of Conformity

Product	duoSHIELD™ ICE NITRILE™ 240 - Powder Free Ambidextrous Non-Sterile 24 cm Nitrile Exam Gloves
Product Codes	65 5121 (XS/6), 65 5122 (S/7), 65 5123 (M/8), 65 5124 (L/9) and 65 5125 (XL/10)
GMDN	40546 (Glove, patient examination, non-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	Butadiene acrylonitrile co-polymer
Product Standards	EN455-1: 2000, EN455-2: 2015, EN455-3: 2015 & EN455-3: 2009
Additional Standards	EN388:1994, EN374-2:1994 (AQL 1.5 achieved by EN455-1), EN374-3:1994 and EN420: 1994 (Product Test Data available on request)

This Product contains no Natural Rubber Latex

CE-Certification of Medical Devices class 1, as per Annex IX of the Council Directive 93/42/EEC. Here: duoSHIELD™ ICE NITRILE™ 240 - Powder Free Ambidextrous Non-Sterile 24 cm Nitrile Exam Gloves, multilingual product codes 65 5121 (XS/6), 65 5122 (S/7), 65 5123 (M/8), 65 5124 (L/9) and 65 5125 (XL/10).

We hereby declare that the above mentioned device complies with the European Medical Device Directive 93/42/EEC and are 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.

SHIELD Scientific B.V.

J.F. Robles
General Manager

Validity of this Declaration: January 1st 2016 until December 31st 2017