EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 763361 R000

Manufacturer: Ansell Healthcare Europe NV

Address:
Boulevard International 55
Brussels, B-1070
Belgium

Single Registration Number: BE-MF-000000691

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-01-05**

Current Issue Date: **2025-02-10**

Starting Validity Date: **2025-02-10**

Expiry Date: **2028-01-04**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Natural rubber latex powder free sterile surgical gloves	Class IIa
Synthetic polyisoprene powder free sterile surgical gloves	Class IIa
Polychloroprene powder free sterile surgical gloves	Class IIa
Composite polymer (polyisoprene + Polychloroprene) powder free sterile surgical gloves	Class IIa
Radiation attenuating polyisoprene powder free sterile surgical gloves	Class IIa
Natural rubber latex glove-in-glove system powder free sterile surgical gloves	Class IIa
Synthetic polyisoprene glove-in-glove system powder free sterile surgical gloves	Class IIa
Nitrile powder free sterile examination gloves	Class Is
Natural rubber latex powder free sterile examination gloves	Class Is
Copolymer powder free sterile examination gloves	Class Is
Sterile Skin Markers	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Natural Rubber Latex Sterile Powder Free Antimicrobial Surgical Glove	See MDR 763362

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-01-05	3598363	Issued
2023-05-10	30000150	Amended ; - Addition of two new sub-contractors - Company name change for a subcontractor - Administrative changes to Device Name in Device Schedule
2024-01-17	30073390	Supplemented – Addition of Natural Rubber Latex Sterile Powder Free Antimicrobial Surgical Glove device.
Current	30297139	Supplemented – Addition of Sterile Skin Markers into the certificate. Amended – Addition of critical sub-contractor.

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