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 and Class IIb implantable devices an 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 Medical Devices

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

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

Starting Validity Date: **2023-01-05**

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

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Device Schedule: Class IIa, Custom-made and other devices

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

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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
Current	3598363	Issued

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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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