# 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 Medical Devices

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

Current Issue Date: **2024-01-17**

Starting Validity Date: **2024-01-17**

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 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 |
| 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 ;<br>- Addition of two new sub-contractors<br>- Company name change for a subcontractor<br>- Administrative changes to Device Name in Device Schedule |
| Current | 30073390 | Supplemented – Addition of Natural Rubber Latex Sterile Powder Free Antimicrobial Surgical Glove device. |

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