By Royal Charter

# EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

## MDR 732238 R000

**Manufacturer:** Medica Europe B.V.

**Address:**
Galliersweg 20
5349 AT Oss
The Netherlands

**Single Registration Number:** NL-PR-000000117

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation.

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: **2020-11-30**

Current Issue Date: **2024-05-16**

Starting Validity Date: **2024-05-16**

Expiry Date: **2025-11-29**

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### Device Schedule: Article 22.3 Systems and Procedure Packs

| Device(s) | Highest Risk Classification within the System or Procedure Pack |
|---|---|
| Procedure Packs - General surgery | Class III |
| Procedure Packs - Cardio-thoracic surgery | Class III |
| Procedure Packs - Orthopaedic procedures | Class III |
| Procedure Packs - Otorhinolaryngology | Class III |
| Procedure Packs - Ophthalmology | Class III |
| Procedure Packs - Gynaecology & obstetrics | Class III |
| Procedure Packs - Urology | Class III |
| Procedure Packs - Neurosurgery | Class III |
| Procedure Packs - Angiography | Class III |
| Procedure Packs - Anaesthesiology | Class III |
| Procedure Packs - Plastic surgery | Class III |
| Procedure Packs - General nursing | Class III |
| Procedure Packs - Biopsy | Class III |
| Procedure Packs - Disposable instruments | Class III |
| For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged. | |

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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 |
|---|---|---|
| 2020-11-30 | 3255167 | First Issue |
| Current | 30051464 | Amended – addition of a new subcontractor and removal of a subcontractor for EtO sterilisation<br>Amended – addition of additional manufacturing site<br>Amended – addition of the SRN number and administrative clarification of the device schedule table |

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