By Royal Charter

EU Quality Assurance Certificate

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

MDR 732238 R001

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: **2025-10-15**

Starting Validity Date: **2025-11-30**

Expiry Date: **2030-11-29**

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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
2024-05-16	30051464	Amended – addition of a new subcontractor and removal of a subcontractor for EtO sterilisation Amended – addition of additional manufacturing site Amended – addition of the SRN number and administrative clarification of the device schedule table
Current	30423670	Re-issued – Certificate renewal

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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.

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