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: Not Available

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-11-30** Date: **2020-11-30** Expiry Date: **2025-11-29**

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By Royal Charter

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Device Procedure Packs:

1. General surgery
2. Cardio-thoracic surgery
3. Orthopaedic procedures
4. Otorhinolaryngology
5. Ophthalmology
6. Gynaecology & obstetrics
7. Urology
8. Neurosurgery
9. Angiography
10. Anaesthesiology
11. Plastic surgery
12. General nursing
13. Biopsy
14. Disposable instruments

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
Current	3255167	First Issue

First Issued: **2020-11-30** Date: **2020-11-30** Expiry Date: **2025-11-29**

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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.
A Member of the BSI Group of Companies.