By Royal Charter

EU Quality Assurance Certificate

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

MDR 734870 R000

Manufacturer: Medica Europe B.V.

Address:
Galliersweg 20
5349 AT Oss
The Netherlands

Single Registration Number: NL-MF-000000118

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 the placing on the market of Class III and Class IIb devices an additional Annex X 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: **2020-11-30**

Current Issue Date: **2023-11-10**

Starting Validity Date: **2023-11-10**

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

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

Device(s)	Risk Classification
Administration Set	Class IIa
Reconstitution device	Class Is
Nasal suction tip	Class Is
Suction tube	Class Is
Medical drape	Class Is
Medical gown	Class Is
Medical equipment cover	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
2020-10-30	3255167	Issued
2021-09-24	3478804	Amended – Correction of first history page entry from 'First Issue' to 'Issued' Supplemented – addition of device, Administration Set Amended – addition of new subcontractor for EtO sterilisation and manufacturing. Single Registration Number added
2022-12-20	3808913	Amended – Administrative update of address for subcontractor supplying manufacture
Current	30051465	Amended – addition of a new subcontractor and removal of a subcontractor for EtO sterilisation

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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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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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