By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 775549 R000

Manufacturer: Rocket Medical PLC

Address:
Sedling Road,
Washington,
NE38 9BZ
United Kingdom

Single Registration Number: GB-MF-000025375

EU Authorised Representative: Rocket Medical GmbH

Address:
Am Rosengarten 48
15566 Schöneiche
Germany

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 and Class IIb implantable devices an 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: **2023-01-05**

Starting Validity Date: **2023-01-05**

Expiry Date: **2028-01-04**

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Device Schedule:

Device(s)	Risk Classification
Needle Guides	Class Is
Obstetrics devices	Class Is
Drainage and fluid collection devices	Class Is
Gynaecological Devices	Class Is
Administration and aspiration filters	Class Is
Drainage and fluid collection devices	Class Im & Is
Cerebrospinal Fluid Pressure monitoring systems	Class Im & Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

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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	3729573	Issued

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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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