By Royal Charter

EU Quality Management System Certificate

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

MDR 778685 R000

Manufacturer: Vortex Surgical, Inc.

Address:
4 Research Park Drive, Suite 124
St. Charles
Missouri
63304
USA

Single Registration Number: US-MF-000022888

EU Authorised Representative: Emergo Europe

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

First Issue Date: **2024-06-17**

Current Issue Date: **2025-03-27**

Starting Validity Date: **2025-03-27**

Expiry Date: **2029-06-16**

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

Device(s)	Risk Classification
Laser Probe and Illumination Devices	Class IIa
Forceps Devices	Class IIa

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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
2024-06-17	3766557	Issued
Current	30363171	Supplemented – Addition of Forceps Devices.

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