By Royal Charter

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 699755**

Issued To: **Vortex Surgical, Inc.**
**680 Crown Industrial Ct, Suite F**
**Chesterfield**
**Missouri**
**63005**
**USA**

In respect of:

**The design and manufacture of sterile single use surgical forceps for retinal surgery.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-05-20** Date: **2019-05-20** Expiry Date: **2024-05-19**

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# EC Certificate - Full Quality Assurance System

**Supplementary Information to CE 699755**

Issued To:

**Vortex Surgical, Inc.**
**680 Crown Industrial Ct, Suite F**
**Chesterfield**
**Missouri**
**63005**
**USA**

| Number | Device Name | Intended Purpose per IFU |
|---|---|---|
| Class IIa | | |
| MD 0105 | ACTU8 Forceps | N/A |

First Issued: **2019-05-20** Date: **2019-05-20** Expiry Date: **2024-05-19**

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# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

# List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

| | |
|---|---|
| Certificate No: | **CE 699755** |
| Date: | **2019-05-20** |
| Issued To: | **Vortex Surgical, Inc.**<br>**680 Crown Industrial Ct, Suite F**<br>**Chesterfield**<br>**Missouri**<br>**63005**<br>**USA** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Emergo Europe<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | **EU Representative** |
| Midwest Sterilization Corp.<br>1204 Lenco Avenue<br>Jackson<br>Missouri<br>63755<br>USA | **ETO Sterilization** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 699755**

Date: **2019-05-20**

Issued To: **Vortex Surgical, Inc.**
**680 Crown Industrial Ct, Suite F**
**Chesterfield**
**Missouri**
**63005**
**USA**

| Date | Reference Number | Action |
|---|---|---|
| Current | 9647802 | First Issue |

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