

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****...making excellence a habit.™**

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

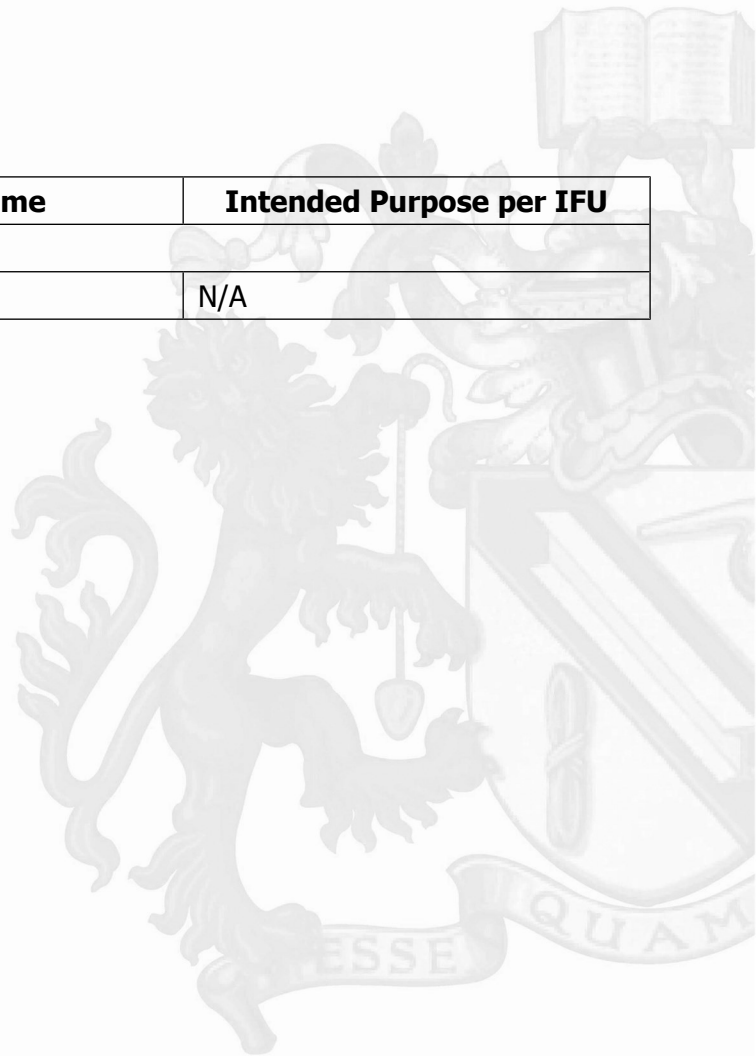
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Supplementary Information to CE 699755

Issued To:

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



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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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680 Crown Industrial Ct, Suite F
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Missouri
63005
USA

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

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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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