By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 57980**

Issued To: **Stereotaxis Inc**
4320 Forest Park Avenue
Suite 100
St Louis
Missouri
63108
USA

In respect of:

Manufacture of Magnetic Navigation Systems (MNS) for clinical diagnostic and therapeutic applications, CardioDrive, Vdrive, Odyssey Workstation and related single-use Peripherals/Accessories.

Those aspects of Annex V related to obtaining and maintaining sterility in the manufacture of the accessories for the above product lines.

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2002-10-14** Date: **2017-10-13** Expiry Date: **2022-10-13**

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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
Isomedix Operations Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
I-TEK Medical Technologies 1837 Buerkle Road White Bear Lake Minnesota 55110 USA	**Control of Sterilization** **Manufacture** **Packaging**
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	**EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
14 October 2002		Initial Issue
15 April 2003		Amendment to include CardioDrive and limited Annex V and remove Guidewires
21 December 2005		Change to address and addition of Sanmina SCI Corp. to the list of sub-contractors as a manufacturing site
31 July 2009	7295043	Addition of Odyssey Workstation and related Peripherals / Accessories to scope and addition of Siemens Manufacturing Company to the List of Significant Subcontractors for the activity of Manufacture.
07 September 2009	7439984	Change of subcontractor manufacturer's name from Enova Medical Technologies to I-TEK Medical Technologies due to an acquisition and subsequent name change.
19 August 2010	7558773	"Vdrive" added to scope. MDSS added to the list of significant subcontractors as EU representative. "Packing" and "Control of Sterilization" added to I-TEK's activities. Removal of Steris Isomedix Services and Sanmina SCI Corporation as significant subcontractors.

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Date	Reference Number	Action
27 September 2010	7582307	Biotest Laboratories and Stereotaxis (Maple Grove) removed from the list of subcontractors.
26 September 2012	7829566	Certificate renewal. Siemens Manufacturing Company remove from the list of subcontractors.
14 January 2013	7929731	Scope clarification to highlight the presence of class Is accessories.
Current	8728170	5yr Renewal plus addition of Isomedix Operations Inc., Minneapolis, MN for ETO Sterilization. Additionally, scope was changed to reduce multiple-use peripherals/accessories as these devices have been discontinued by the manufacturer.