By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 572030**

Issued To: **Smisson-Cartledge Biomedical, LLC**
487 Cherry Street, Third Street Tower
Third Floor
Macon
Georgia
31201
USA

In respect of:

Design and manufacture of an infusion pump used with a single-use sterile cassette and related accessories including single-use sterile tubing line sets and reservoir.

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 February 2012** Date: **31 January 2017** Expiry Date: **31 January 2022**

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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 572030**
Date:	**31 January 2017**
Issued To:	**Smisson-Cartledge Biomedical, LLC** **487 Cherry Street, Third Street Tower** **Third Floor** **Macon** **Georgia** **31201** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	**EU Representative**
Ethox Medical, LLC 2710 Northridge Drive NW, Suite A Grand Rapids Michigan 49544 USA	**Finished Device Supplier**
Iuvo BioScience - Rush, LLC 7500 West Henrietta Road Rush New York 14543 USA	**Sterilization**

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Subcontractor:	**Service(s) supplied**
Medical Solutions, Inc. 3901 Centerview Drive, Suite L Chantilly Virginia 20151 USA	**Distribution** **Final Inspection** **Purchasing** **Testing**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Finished Device Supplier**
Midwest Sterilization Corporation P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA	**Sterilization**

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Subcontractor:	**Service(s) supplied**
Sparton Medical Systems 22740 Lunn Road Strongsville Ohio 44149 USA	**Design** **Manufacture**
Sterigenics International, Inc. 2015 Spring Road Suite 650 Oak Brook Illinois 60523 USA	**Sterilization**
Vention Medical, Inc. 520 Watson SW Grand Rapids Michigan 49504 USA	**Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
01 February 2012	7649466	First Issue
08 September 2015	8413500	Re-issue due to addition of 'Ethox Medical, LLC, Michigan 49544' to list of significant subcontractors for 'ETO Sterilization & Manufacture'. Addition of 'Medtronic Mexico S.de R.L.de CV, Mexico' for 'ETO Sterilization & Manufacture' and 'Medical Solutions, Inc., Virginia 20151' for 'Final inspection, Testing, Distribution & Purchasing'. Also removal of significant subcontractor, 'Sorin Group USA, Inc.' & 'Ethox International, NY 14204'.

EC Certificate - Full Quality Assurance System Certificate History

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31 January 2017	8594854	Certificate Renewal and rewording of address to include "Third floor." Addition of significant subcontractors for sterilization – Vention Medical, Inc., Grand Rapids, USA. Sterigenics International, Inc., Illinois, USA. Midwest Sterilization Corporation, Missouri, USA. Subcontractor Medtronic Mexico change of service supplied from ETO Sterilization & Manufacture to Finished Device Supplier. Subcontractor Ethox Medical, LLC, Michigan change of service supplied from ETO Sterilization & Manufacture to Finished Device Supplier. Addition of significant subcontractors for sterilization – Iuvo BioScience – Rush, LLC, New York, USA.