



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

No. Issued To: CE 572030

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

...making excellence a habit.[™] Page 1 of 1

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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.





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: Date:

31 January 2017

CE 572030

Issued To:

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

Subcontractor:

Service(s) supplied EU Representative

Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands

Ethox Medical, LLC 2710 Northridge Drive NW, Suite A Grand Rapids Michigan 49544 USA

Iuvo BioScience - Rush, LLC 7500 West Henrietta Road Rush New York 14543 USA Finished Device Supplier

Sterilization

...making excellence a habit.™

Page 1 of 3





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:

CE 572030

31201 USA

Certificate No: Date:

Issued To:

31 January 2017 Smisson-Cartledge Biomedical, LLC 487 Cherry Street, Third Street Tower Third Floor Macon Georgia

Subcontractor:

Medical Solutions, Inc. 3901 Centerview Drive, Suite L Chantilly Virginia 20151 USA

Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico

Midwest Sterilization Corporation P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA Service(s) supplied

Distribution Final Inspection Purchasing Testing

Finished Device Supplier

Sterilization

...making excellence a habit.[™]

Page 2 of 3





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: Date:

Issued To:

49504 USA CE 572030 31 January 2017 Smisson-Cartledge Biomedical, LLC 487 Cherry Street, Third Street Tower Third Floor Macon Georgia 31201 USA

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

...making excellence a habit.™

Page 3 of 3





EC Certificate - Full Quality Assurance System Certificate History

Certificate No:

CE 572030

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

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'.

...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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.





EC Certificate - Full Quality Assurance System Certificate History

Certificate No:

CE 572030

Date:

Issued To:

31 January 2017 Smisson-Cartledge Biomedical, LLC 487 Cherry Street, Third Street Tower Third Floor Macon Georgia 31201 USA

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.
		supplied from ETO Sterilization & Manufacture to Finished Device Supplier. Addition of significant subcontractors for sterilization –
		Iuvo BioScience – Rush, LLC, New York, USA.

...making excellence a habit." Page 2 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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.