EC Certificate - Production Quality Assurance

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

No. **CE 620856**

Issued To: **TIDI Products LLC**
570 Enterprise Drive
Neenah
Wisconsin
54956
USA

In respect of:

Those aspects relating to securing and maintaining sterility in the manufacture of non-invasive patient drapes, urology drain bags, equipment covers and adhesive skin attachment and securement device for anchoring catheters, tubes and 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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-04-02** Date: **2020-03-10** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 620856

Issued To:

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Number	Device Name
Class I Sterile	
MD0101	PICC/CVC central line securement
	Foley securement
	Nasal gastric securement
	Universal securement
	Instrument/equipment drape
	Microscope cover
	Urological fluid funnel
	Foot switch cover
	Camera cover
	Slush/warming machine covers
	Ultrasound probe covers
	Navi-Crani drape
	Z Patient drape

First Issued: **2015-04-02** Date: **2020-03-10** Expiry Date: **2024-05-26**

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

List of Significant Subcontractors

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

Certificate No:	**CE 620856**
Date:	**2020-03-10**
Issued To:	**TIDI Products LLC** **570 Enterprise Drive** **Neenah** **Wisconsin** **54956** **USA**

Subcontractor:	**Service(s) supplied**
Changshu Yushan Protection Products Co., Ltd. Building No. 1, Section A Maqiao Industrial Square Tonggang Road Changshu EDZ Jiangsu 215513 China	**Manufacture**
Medical Device Safety Service GmbH (MDSS) Schiffgraben 41 30175 Hannover Germany	**EU Representative**
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Radiation (Gamma Sterilization)**

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By Royal Charter

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List of Significant Subcontractors

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

Certificate No:	**CE 620856**
Date:	**2020-03-10**
Issued To:	**TIDI Products LLC** **570 Enterprise Drive** **Neenah** **Wisconsin** **54956** **USA**

Subcontractor:	**Service(s) supplied**
STERIS Sterilization Technologies (Suzhou) Ltd No. 26 Xinchang Road Suzhou Industrial Park Jiangsu 215125 China	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 620856**

Date: **2020-03-10**

Issued To: **TIDI Products LLC**
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Date	Reference Number	Action
02 April 2015	8238929	First issue.
12 February 2019	8898820	Traceable to NB 0086. Administrative Subcontractor Service wording update for: Sterigenics International LLC, Illinois, 60523 from "Sterilization" to "Gamma Sterilization".
11 December 2019	9756415	Extension to scope to include class I sterile non-invasive patient drapes, equipment covers and urology drain bags. Addition of significant sub-contractors; Changshu Yushan Protection Products, Synergy Health (Suzhou) Sterilization Technologies and Centurion Medical Products. Change of EU Rep from Blue Box Medical Limited to MDSS (Medical Device Safety Service GmbH). Correction to gamma sterilization sub-contractor address from Sterigenics US, LLC. 2015 Spring Road, Illinois to Sterigenics US, LLC. 1003 Lakeside Drive, Illinois. Removal of product name "Grip-Lok" from scope of certification and replaced with generic scope wording "adhesive skin attachment and securement device". Inclusion of supplementary product information page.
10 March 2020	3146563	Certificate renewal

EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
07 December 2021	3558864	Update subcontractors: Name of EU rep updated format to Medical Device Safety Service GmbH (MDSS). Centurion Sterilization Services removed. Name of sterilizer updated from Synergy Health (Suzhou) Sterilization Technologies Ltd, to STERIS Sterilization Technologies (Suzhou) Ltd.

Inspiring trust for a more resilient world.

07 December 2021

TIDI Products LLC
570 Enterprise Drive
Neenah
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54956
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 620856	93/42/EEC Annex V	3558864	Update subcontractors: Name of EU rep updated format to Medical Device Safety Service GmbH (MDSS). Centurion Sterilization Services removed. Name of sterilizer updated from Synergy Health (Suzhou) Sterilization Technologies Ltd, to STERIS Sterilization Technologies (Suzhou) Ltd.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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