

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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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 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

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

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:

Certificate No: **CE 620856**
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Subcontractor:	Service(s) supplied
Centurion Medical Products Corporation 301 Catrell Drive Howell, MI 48843 USA	ETO Sterilization
Changshu Yushan Protection Products Co., Ltd. Building No. 1, Section A Maqiao Industrial Square Tonggang Road Changshu EDZ Jiangsu 215513 China	Manufacture
MDSS (Medical Device Safety Service GmbH) Schiffgraben 41 30175 Hanover Germany	EU Representative

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Subcontractor:

Service(s) supplied

Sterigenics US, LLC
1003 Lakeside Drive
Gurnee
Illinois
60031
USA

Gamma Sterilization

Synergy Health (Suzhou)
Sterilization Technologies 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**
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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.
Current	3146563	Certificate renewal