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.

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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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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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 620856**

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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

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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.
20 October 2026	30378695	Removal of a subcontractor for manufacture and a subcontractor for sterilisation.

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Inspiring trust for a more resilient world.

20 October 2026

TIDI Products LLC
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

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) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 620856	93/42/EEC Annex V	30378695	Removal of a subcontractor for manufacture and a subcontractor for sterilisation.

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,

Graeme Tunbridge
Senior Vice President, Medical Devices

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