

# UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

**No.** UKCA 757280  
**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 Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-12-07**

Date: **2021-12-07**

Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: 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.

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## Supplementary Information to UKCA 757280

Issued To: **TIDI Products, LLC**  
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Device Code	Device Name	Intended purpose per IFU
<b>Class Is</b>		
MD 0101	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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## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No: **UKCA 757280**  
Date: **2021-12-07**  
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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Changshu Yushan Protection Products Co., Ltd. Building No. 1, Section A Maqiao Industrial Square Tonggang Road Changshu EDZ Jiangsu 215513 China	<b>Manufacture</b>
Emergo Consulting (UK) Limited c/o Cr360 – UL International Compass House, Vision Park Histon Cambridge CB24 9BZ United Kingdom	<b>UK Responsible Person</b>
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	<b>Radiation (Gamma Sterilization)</b>

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**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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## Certificate History

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Date	Reference Number	Action
Current	3513692	First Issue. Traceable to CE 620856.

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