

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]

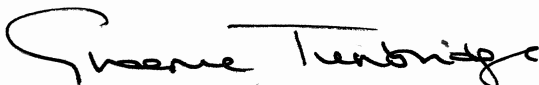
No. UKCA 757280
Issued To: TIDI Products, LLC
570 Enterprise Drive
Neenah
Wisconsin
54956
USA

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility of noninvasive 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):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

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

Date: **2024-08-29**

Expiry Date: **2029-05-26**

...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 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.

UKCA Certificate - Production Quality Assurance

Supplementary Information to UKCA 757280

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

Device code	Device name	Intended purpose per IFU
Class Is		
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	---

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

Date: **2024-08-29**

Expiry Date: **2029-05-26**

...making excellence a habit.™

UKCA Certificate - Production Quality Assurance

Certificate History

Certificate No: **UKCA 757280**
Date: **2024-08-29**
Issued To: **TIDI Products, LLC**
570 Enterprise Drive
Neenah
Wisconsin
54956
USA

Date	Reference Number	Action
2021-12-07	3513692	First Issue. Traceable to CE 620856.
2024-05-14	30180934	Certificate Renewal.
Current	30247232	Addition of subcontractors for sterile barrier packaging and sterilization.

...making excellence a habit.™