By Royal Charter

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: **2024-05-14** Expiry Date: **2029-05-26**

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Supplementary Information to UKCA 757280

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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	---

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UKCA Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
2021-12-07	3513692	First Issue. Traceable to CE 620856.
Current	30180934	Certificate Renewal.

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