EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 766741 R000

Manufacturer: TIDI Products LLC

Address:
570 Enterprise Drive
Neenah
Wisconsin
54956
USA

Single Registration Number: US-MF-000012287

EU Authorised Representative: MDSS GmbH

Address:
Schiffgraben 41
30175 Hannover
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-12-06**

Current Issue Date: **2024-03-07**

Starting Validity Date: **2024-03-07**

Expiry Date: **2028-12-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile Scalpels with Safety Systems, Single-Use	Class IIa
Sterile Securement Devices	Class Is
Sterile Instruments and Equipment Covers	Class Is
Sterile Surgical Drapes	Class Is
Sterile Urology Drainage and Fluid Collection Devices	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-12-06	3636456	Issued
Current	30079921	Supplemented – Addition of Class Is device group Sterile Urology Drainage and Fluid Collection Devices

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