EU/UK/AU/CH Declaration of Conformity
DC0040 Rev. 10

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Manufacturer Information:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956, USA SRN: US-MF-000012287
Person Responsible for Regulatory Compliance (PRRC):	Chris Rahn, Senior Director Quality & Regulatory
European Union (EU) Authorized Representative Contact Information:	MDSS GmbH Schiffgraben 41 30175 Hannover, Germany Phone: (+49) 511 6262 8630 SRN: DE-AR-000005430
United Kingdom (UK) Responsible Person Contact Information:	Emergo Consulting (UK) Limited c/o Cr360 UL International Compass House, Vision Park Histon Cambridge CB24 9BZ, United Kingdom Phone: +44(0) 1223 772 671
Swiss (CH) Authorized Representative Contact Information:	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau, Switzerland CHRN: CHRN-AR-20001035.
Product identification:	Non-Sterile Grip-Lok adhesive skin attachment and securement device for anchoring catheters, tubes, and lines.
Technical File No.:	TF-0020 TIDI Products Grip-Lok Securement
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate
EU Legislation and Conformity Assessment Procedure:	Annex II & Annex III: Technical documentation including PMS of Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.
UK Legislation and Conformity Assessment Procedure:	UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). Conformity to Part II of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002).
Australia (AU) Legislation and Conformity Assessment Procedure:	Clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002
CH Legislation and Conformity Assessment Procedure:	Annex II & Annex III: Technical documentation including PMS of Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.
Intended purpose:	• The intended use of the securement devices is for use in the general population, for adhesive securement of the catheter hub, tube, or line to the patient's skin.

EU/UK/AU/CH Declaration of Conformity
DC0040 Rev. 10

	• The intended use of the Tracheostomy Ties is to hold a tracheal tube or oxygen cannula in place. • The intended use of the Pulse Oximeter Probe Wrap is to hold an external device securely in place against a body part	
EMDN Code:	EMDN code for Securement: V9099 Various devices not included in other classes	
Basic UDI-DI:	Basic UDI-DI for Securement: Nasal 0618125TF-0020-AWL Breathing 0618125TF-0020-BWN Urology 0618125TF-0020-CWQ General 0618125TF-0020-DWS Tracheostomy 0618125TF-0020-EWU Pulse oximeter 0618125TF-0020-FWW	
Device Classification/ Rule in EU/CH:	Risk Class I	Rule 1
Device Classification/ Rule in UK:	Risk Class I	Rule 1
Device Classification/ Rule in Australia (AU):	Class 1	Rule 2.1
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	NA	
EC Certificate:	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
UKCA Certificate:	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 29 May 2023
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 29 May 2023
Notified Body for QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands NB No. 2797	
Notified Body for EU Conformity Assessment: ***(if applicable)***	NA	

EU/UK/AU/CH Declaration of Conformity
DC0040 Rev. 10

Approved Body for UK Conformity Assessment*: (if applicable*)	NA

For European Union (Non-sterile products)

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC.
The undersigned hereby declares, on behalf of TIDI Products, LLC, that the medical devices referenced in this declaration comply with the European Medical Devices Regulation; MDR (EU) 2017/745. We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

For United Kingdom:

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC.
The undersigned hereby declares, on behalf of TIDI Products, LLC, that the medical devices referenced in this declaration comply with the UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).). We explicitly designate Emergo Consulting (UK) Limited to act as our sole Responsible Person in the UK for the above indicated products.

For Australia (Non-sterile products):

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC. The undersigned hereby declares, on behalf of TIDI Products, LLC, that each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, and the classification rules before being supplied under clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods Administration Medical Device Regulation 2002.

For Switzerland:

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC. The undersigned hereby declares, on behalf of TIDI Products, LLC, that the medical devices referenced in this declaration comply with the applicable parts of the MedDO. These are class I medical devices that declare conformity to Regulation (EU) 2017/745 (MDR) and class I sterile medical devices according to the Directive 93/42/EEC. We explicitly designate MDSS CH GmbH to act as our sole Authorised Representative in Switzerland for the above indicated products.

Signed on behalf of TIDI Products LLC, in Neenah, WI.

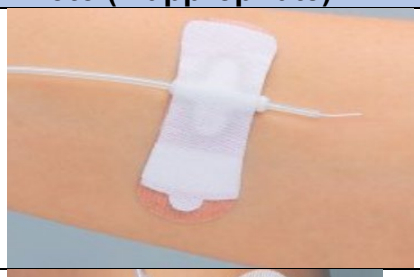
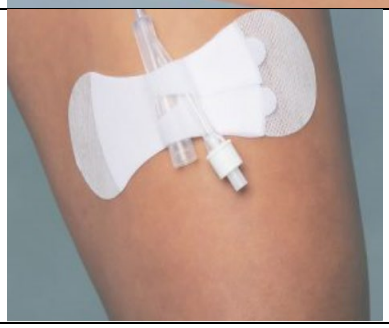
Name of TIDI Representative; Javorka Spalevic	**Title, Function**	**Date**
Approval: Javorka Spalevic	**Approval:** Regulatory Product Manager	08/20/2024

EU/UK/AU/CH Declaration of Conformity
DC0040 Rev. 10

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies (in EU/ UK/ AU/CH)			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
1100DTS-NSB	OEM Bulk Pack Tape Strip	56631	00618125135189
3200S-NSB	Small Universal Securement Device	56631	00618125135097
3300M-NSB	Medium Universal Securement Device	56631	00618125134724
3300MART-NSB	Arterial and Peripheral IV Catheter Securement Device	56631	00618125135363
3300MWA-NSB	Medium Universal Securement Device with Wide Silicone Adhesive area	56631	00618125135110
3300MW-TA-3-NSB	Securement Device for Universal Fixation	56631	00618125190249
3301MCS-LT-NSB	Medium Catheter Securement for Stingray® Connector	56631	00618125135233
3301MCS-HL-NSB	Medium Catheter Securement for PICC/CVC Applications	56631	00618125135219
3400L-NSB	Large Universal Securement Device	56631	00618125135158
3400LFC-NSB	Foley Catheter Securement Device	57982	00618125135165
3601CVC-NSB	Universal CVC Securement Device	56631	00618125135226
3604MCS-TA-NSB	Catheter Fixation for Arrow® PICC/CVC	56631	00618125140916
MCGLPICC-NSB	Catheter Fixation for MedComp® PICC/CVC	56631	00618125177486
03.06.70.10	Medium Sized Securement Device	56631	00618125135318
01.60.70.10	Catheter Securement for Bard® PICC & CVC	57982	00618125143863
A1213	Grip-Lok® OEM Bulk Package Catheter Securement for B. Braun PICC	56631	00618125135509
020153831	Medium Securement for Baxter	56631	00618125135271
6554	Pulse Oximeter Probe Wraps	56631	00190676001859
6550	Incontinence Sheath Holders	34929	00190676001842
8197S	Foam Tracheostomy Ties, S	35815	00190676002184
8197M	Foam Tracheostomy Ties, M	35815	00190676002191
8197L	Foam Tracheostomy Ties, L	35815	00190676002207
8197XL	Foam Tracheostomy Ties, XL	35815	00190676002214
8196S	Posey® Secure Tie for Tracheostomy Tube – Small	35815	00190676002221
8196M	Posey® Secure Tie for Tracheostomy Tube – Medium	35815	00190676002238
8196L	Posey® Secure Tie for Tracheostomy Tube – Large	35815	00190676002245

EU/UK/AU/CH Declaration of Conformity
DC0040 Rev. 10

Product Model Numbers, Description, and GMDN code to which this declaration applies (in UK)		
Model Number (REF)	**Product Name**	**GMDN**
6554	Pulse Oximeter Probe Wraps	56631
6550	Incontinence Sheath Holders	34929
8197S	Foam Tracheostomy Ties, S	35815
8197M	Foam Tracheostomy Ties, M	35815
8197L	Foam Tracheostomy Ties, L	35815
8197XL	Foam Tracheostomy Ties, XL	35815
8196S	Posey® Secure Tie for Tracheostomy Tube – Small	35815
8196M	Posey® Secure Tie for Tracheostomy Tube – Medium	35815
8196L	Posey® Secure Tie for Tracheostomy Tube – Large	35815

Product Name	Photo (if appropriate)
Small universal securement device	
Foley Catheter Securement Device	
Pulse oximeter probe wraps	
Posey® Secure Tie for Tracheostomy Tube	

EU/UK/AU/CH Declaration of Conformity
DC0040 Rev. 10

Foam Tracheostomy Ties	
Incontinence Sheath Holders	

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
56631	Wearable percutaneous catheter/tube holder
57982	Urinary catheter holder
34929	Urinary incontinence penis sheath/port, single-use, non-sterile
35815	Endotracheal tube holder