EU/UK/AU/CH Declaration of Conformity
DC0001 Rev. 26

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, VP 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:	Sterile Grip-Lok adhesive skin attachment and securement device for anchoring catheters, tubes, and lines (Securement, sterile)
Technical File No.:	TF-0020: TIDI Products Grip-Lok Securement
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photos, where appropriate
EU Legislation and Conformity Assessment Procedure:	Medical Device Regulation (EU) 2017/745, Annex IX Chapter I and III. Annex IX: Conformity Assessment based on a quality management system and on assessment of technical documentation of Medical Device 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 V (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:	Medical Device Regulation (EU) 2017/745, Annex IX Chapter I and III.

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Intended purpose:	For use in the general population, for adhesive securement of the catheter hub, tube, or line to the patient's skin.	
EMDN Code:	EMDN code for Securement: V9099 Various devices not included in other classes	
Basic UDI-DI:	Nasal 0618125TF-0020-AWL Urology 0618125TF-0020-CWQ General 0618125TF-0020-DWS	
Device Classification/ Rule in EU/CH:	Class 1 Sterile	Rule 1
Device Classification/ Rule in UK:	Class I Sterile	Rule 1
Device Classification/ Rule in Australia (AU):	Class 1 Sterile	Rule 2.1
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	N/A	
MDR Certificate:	Number: MDR 766741	Issue Date: 2023-12-06
UKCA Certificate:	Number: UKCA 757280	Issue Date: 2021-12-07
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 2023-05-29
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 2023-05-29
Notified Body for QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
Notified Body for EU Conformity Assessment:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
Approved Body for UK Conformity Assessment*:*	BSI UK Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, United Kingdom MK5 8PP Approved Body Number: 0086	

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For European Union (Sterile devices):

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 Medical Device Regulation (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 (Sterile devices):

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 (Sterile devices):

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 declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures under clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods Administration Medical Device Regulation 2002.

For Switzerland (Sterile devices):

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 Med DO. These are class Is medical devices that comply with the Medical Device Regulation (EU) 2017/745. 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. 54956

Name of TIDI Representative; Javorka Spalevic	**Title, Function**	**Date**
Approval: Javorka Spalevic	**Approval:** Regulatory Product Manager	11/15/2024

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Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
2100ANG	Small Nasogastric Securement Device	36053	00618125134601
2100NGH	Small Nasogastric Hydrocolloid Securement Device	56631	00618125134618
2200NUZA	Extra Small Securement Device with Zinc-Oxide Adhesive	56631	00618125134809
3200S	Small Universal Securement Device	56631	00618125134656
3300M	Medium Universal Securement Device	56631	00618125134670
3300MART	Medium Peripheral IV and Arterial Catheter Securement Device	56631	00618125135356
3300MART-KIT-2	Medium Winged Peripheral IV and Arterial Catheter Securement Device and Dressing Kit	56631	00618125177097
3300MEPI	Medium Universal Catheter Securement Device	56631	00618125134687
3300MIV	Medium Peripheral IV and Arterial Catheter Securement Device	56631	00618125134816
3300MWA	Medium Universal Securement with Wide Silicone Adhesive Area	56631	00618125134748
3300MW-TA-3	Universal Fixation	56631	00618125135455
3301MCS-BD	Medium Securement Device for the BD Arterial Cannula with FloSwitch™	56631	00618125134823
3301MCS-HL	Medium Catheter Securement for PICC/CVC Applications	56631	00618125134939
3303MCS-TA	Medium Catheter Securement Device for Arrow® PICC/CVC	56631	00618125134847
3304MCS-BA	Medium Catheter Securement Device for Bard® PICC and CVC	56631	00618125134854
3306MCS-NA	Medium Catheter Securement Device for Navilyst Medical Xcela® PICC	56631	00618125134953
3308MCS-MC	Medium Securement Device for Medcomp® Dialysis Catheter	56631	00618125134861
3400L	Large Universal Securement Device	56631	00618125134755
3400LFC	Large Foley Catheter Securement Device	57982	00618125134779
3401LNG	Large Nasogastric Tube Securement Device	36053	00618125134991

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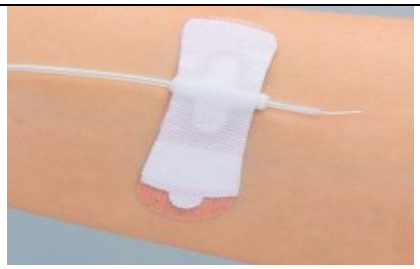
Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
3600PFC	Small Foley Catheter Securement Device	57982	00618125134892
3601CVC	Medium Universal PICC and CVC Securement Device	56631	00618125135011
3604MCS-TA-1	Catheter Fixation for Arrow® PICC/CVC	56631	00618125160945
3300MIV-KIT-2	Medium Winged Peripheral IV and Arterial Catheter Securement Device and Dressing Kit	56631	00618125141470
MCGLPICC	Catheter Fixation for MedComp® PICC/CVC	56631	00618125177585
3200S-10PK	Small Universal Securement Device	56631	10618125192202
3300M-10PK	Medium Universal Securement Device	56631	10618125192196
3400L-10PK	Large Universal Securement Device	56631	10618125192189
3300MWA-10PK	Medium Universal Securement with Wide Silicone Adhesive Area	56631	10618125192141
3400LFC-10PK	Large Foley Catheter Securement Device	57982	10618125192172
3309MCS-TA-2	Catheter Fixation for ARROW® PICC/Midline	56631	00618125160365

Product Name	Photo (if appropriate)
Peripheral IV & Arterial Catheter Securement Device	
Small securement device	

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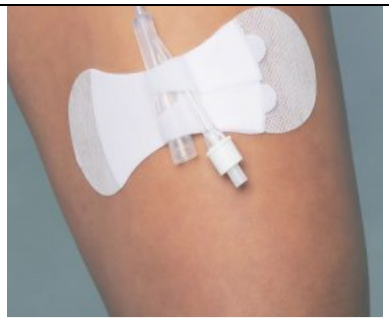
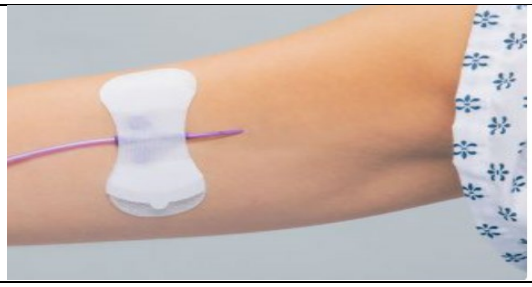
Foley Catheter Securement Device	
Medium Universal Securement with wide silicone adhesive area	

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
56631	Wearable percutaneous catheter/tube holder
57982	Urinary catheter holder
36053	Nasogastric tube holder, noninvasive