Declaration of Conformity DC0040 Rev. 06

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

Manufacturer Information Name, Address, SRN:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA	SRN: US-MF-000012287
Name of responsible person (PRRC) or designee:	Name: Steve Kahn	Title: VP of Quality and Regulatory
Authorized Representative Contact Information:	Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover Germany	SRN: DE-AR-000005430
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.	
Technical File No.:	TF-0020 TIDI Products Grip-Lok Securement	
Product Identification:	Non-Sterile Grip-Lok adhesive skin attachment and securement device for anchoring catheters, tubes, and lines.	
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate.	
Basic UDI-DI, EMDN and Intended purpose:	The intended use of the General, Intravascular, Foley, and Nasal securement devices is as an adhesive skin attachment stabilization and securement device for anchoring catheters, tubes, lines and other catheter systems and components securely in place. EMDN code for Securement: V9099 Various devices not included in other classes 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:	Risk Class I	Rule 1
Reference to Common Specifications:	N/A	
EC Certificate: *If self-declared add "N/A Self-Declared".*	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared

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Quality Management Certificate:	Number: FM 536366	Effective Date: 29 May 2020
Notified Body Information For QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	

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.

Signed for on behalf of TIDI Products LLC, in Lincolnshire, IL.

Name of Authorized Person:	**Title:**	**Date:**
Approval: Javorka Spalevic	Sr. Regulatory Affairs Specialist	04/26/2022

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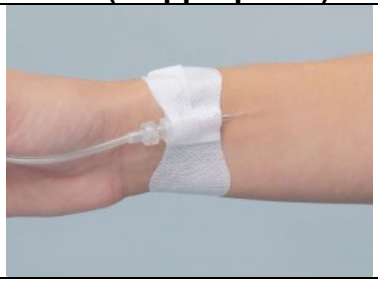
Model Number (REF)	Product Name	GMDN	UDI-DI
1100DTS-NSB	OEM Bulk Pack Tape Strip	56631	00618125135189
3200S-NSB	Small Universal Securement Device for lines and tubes sized 4.5 -13.5 fr	56631	00618125135097
3300M-NSB	Medium Universal Securement Device for lines and tubes sized 9-24 fr	56631	00618125134724
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
3400L-NSB	Large Universal Securement Device for lines and tubes sized 16-40 fr	56631	00618125135158
3400LFC-NSB	Foley Catheter Securement Device for 2- & 3-way Foley Catheters sized 12-30 fr	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
3309MCS-TA-NSB	Catheter Fixation for Arrow® PICC/ CVC	56631	00618125135141
A1213	Catheter Securement for B. Braun PICC	56631	00618125135509
020153831	Medium Securement for Baxter	56631	00618125135271
6554	Posey Pulse Oximeter Probe Wrap	56631	00190676001859
6550	Posey Incontinence sheath holders	34929	00190676001842
8197S	Posey Foam Trach ties - Small	35815	00190676002184
8197M	Posey Foam Trach ties - Medium	35815	00190676002191
8197L	Posey Foam Trach ties - Large	35815	00190676002207
8197XL	Posey Foam Trach ties – Extra large	35815	00190676002214
8141	Posey IV Shield	56631	00190676002894
8143	Posey Catheter tube holder straps	56631	00190676003211
8196S	Secure Tie for Tracheostomy Tube – Small	35815	00190676002221
8196M	Secure Tie for Tracheostomy Tube - Medium	35815	00190676002238
8196L	Secure Tie for Tracheostomy Tube - Large	35815	00190676002245

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

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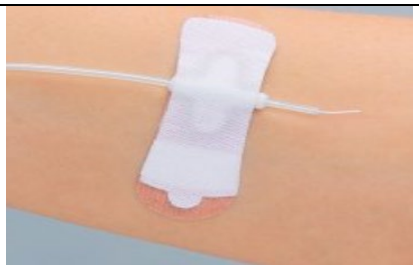
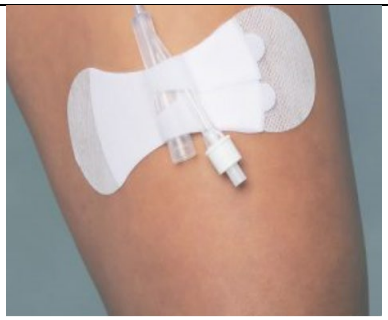
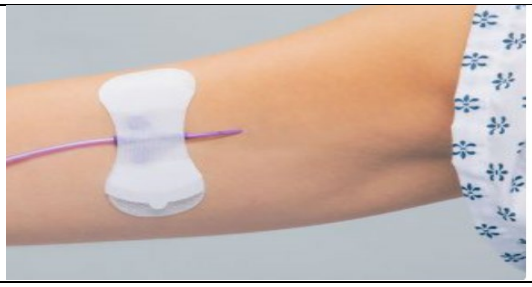
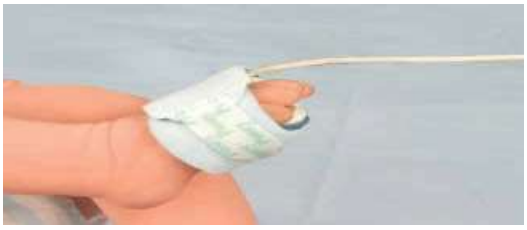
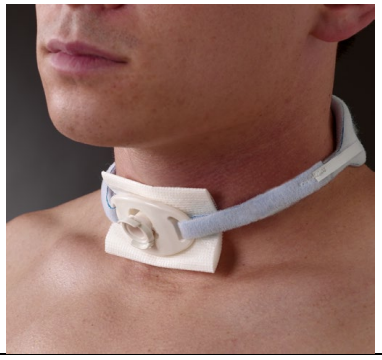
Small securement device	
Foley Catheter Securement Device for 2- & 3-way Foley Catheters sized 12-30 fr	
Medium Universal Securement Device with wide silicone adhesive area	
Posey pulse oximeter probe wrap	
Posey Foam Trach ties	

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Secure Tie for Tracheostomy Tube	
Posey Catheter Tube Holder Straps	
Posey Incontinence Sheath Holders	

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