



Declaration of Conformity DC0040 Rev. 02

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: TBD												
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:	<p>The securement family of devices are intended for use in the general population. 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. Indications include securement for: intravascular catheters, PICC/CVC central lines, urethral catheters, tracheostomy tubes, pulse oximeters, oxygen catheters, nasal catheters, drainage lines, gastrostomy tubes and lines/tubes/catheters in general.</p> <p>The intended use of the Tracheostomy Ties is used 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 to be held securely in place against a body part.</p> <p>EMDN code for Securement: V9099 Various devices not included in other classes</p> <p>Basic UDI-DI for Securement:</p> <table> <tr> <td>Nasal</td> <td>0618125TF-0020-AWL</td> </tr> <tr> <td>Breathing</td> <td>0618125TF-0020-BWN</td> </tr> <tr> <td>Urology</td> <td>0618125TF-0020-CWQ</td> </tr> <tr> <td>General</td> <td>0618125TF-0020-DWS</td> </tr> <tr> <td>Tracheostomy</td> <td>0618125TF-0020-EWU</td> </tr> <tr> <td>Pulse oximeter</td> <td>0618125TF-0020-FWW</td> </tr> </table>		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
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													



Declaration of Conformity DC0040 Rev. 02

Device Classification/Rule:	Risk Class I	Rule 1
Reference to Common Specifications:	N/A	
EC Certificate: <i>If self-declared add "N/A Self-Declared".</i>	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
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	
<p>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.</p>		
Signed for on behalf of TIDI Products LLC, in Neenah, WI.		
Name of Authorized Person:	Title:	Date:
Approval: <i>Javoroka Spalevic</i>	Sr. Regulatory Affairs Specialist	17 Aug 2021




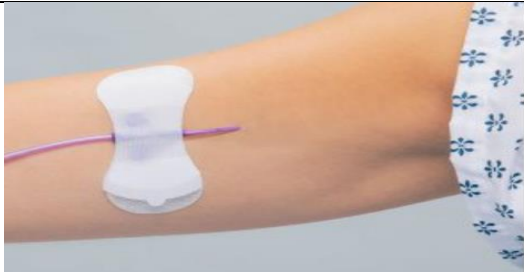







Declaration of Conformity DC0040 Rev. 02

Model Number (REF)	Product Name	GMDN	UDI-DI
1100DTS-NSB	OEM Bulk Pack Tape Strip	56631	00618125135189
2200NUZA-NSB	Extra small securement device with zinc oxide adhesive	56631	10618125176929
2800FCS-NSB	Foley Catheter Securement Device	56631	10618125135490
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
3300MART-NSB5	Arterial and Peripheral IV Catheter Securement Device	56631	00618125135370
3300MEPI-NSB	Epidural Catheter Securement Device	56631	00618125135103
3300MIV-NSB	Peripheral IV & Arterial Catheter Securement Device	56631	10618125135070
3300MIV-NSB5	Peripheral IV & Arterial Catheter Securement Device	56631	00618125135295
3300MWA-NSB	Medium Universal Securement Device with wide silicone adhesive area	56631	00618125135110
3300MW-NSB	Medium Universal Securement with wide silicone adhesive area	56631	00618125134731
3301MCS-HL-NSB	Medium Catheter Securement for PICC/CVC Applications	56631	00618125135219
3301MCS-LT-NSB	Medium Catheter Securement for Stingray® Connector	56631	00618125135233
3303MCS-TA-NSB	Universal Securement Device	56631	10618125135124
3304MCS-BA-NSB	Universal Securement Device	56631	00618125134854
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
3500DFN-NSB	Dialysis Fistula Needle Securement Device	56631	10618125135179
3601CVC-NSB	Universal CVC Securement Device	56631	00618125135226
3601CVC-NSB5	Universal CVC Securement Device	56631	00618125135660
3604MCS-TA-NSB	Catheter Fixation for Arrow® PICC/CVC	56631	00618125140916
MCGLPICC-NSB	Catheter Fixation for MEDCOMP® PICC/CVC	56631	00618125177486
ZL2003MW-NSB	Z lok OEM Bulk Package	56631	00618125135196
03.06.70.10	Medium sized Securement Device	56631	00618125135318
01.60.70.10	Catheter Securement for Bard® PICC & CVC	57982	00618125143863
6554	Posey Pulse Oximeter Probe Wrap	57982	00190676001859
6550	Posey Incontinence sheath holders	34929	00190676001842
8197S	Posey Foam Trach ties - Small	57982	00190676002184
8197M	Posey Foam Trach ties - Medium	57982	00190676002191
8197L	Posey Foam Trach ties - Large	57982	00190676002207



Declaration of Conformity DC0040 Rev. 02

Model Number (REF)	Product Name	GMDN	UDI-DI
8197XL	Posey Foam Trach ties – Extra large	57982	00190676002214
8141	Posey IV Shield	57982	00190676002894
8143	Posey Catheter tube holder straps	57982	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)
Arterial and Peripheral IV Catheter Securement Device	
Extra 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	

<p>Posey pulse oximeter probe wrap</p>	
<p>Posey Foam Trach ties</p>	
<p>Dialysis Fistula Needle Securement Device</p>	
<p>Universal CVC Securement Device</p>	
<p>Secure Tie for Tracheostomy Tube</p>	

Declaration of Conformity DC0040 Rev. 02

<p>Posey Catheter Tube Holder Straps</p>	 <p>8143</p>
<p>Posey Incontinence Sheath Holders</p>	 <p>6660</p>

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