




Declaration of Conformity DC0002 Rev.06

Manufacturer and Contact:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956	Management Representative: Amanda Altan Regulatory Affairs Manager
Authorized Representative:	MDSS GmbH Schiffgraben 41 30175 Hannover, Germany	Telephone: (+49)-511-6262 8630
Conformity Assessment Procedure:	Annex VII of MDD 93/42/EEC Council Directive as amended by directive 2007/47/EC	
Technical File No.:	TF-0020 TIDI Products Grip-Lok Securement	
Product Scope:	Non-Sterile Grip-Lok adhesive skin attachment and securement device for anchoring catheters, tubes, and lines.	
Model Numbers:	See following page(s) for model numbers, GMDNs, and descriptions.	
Device Classification:	Class 1	Rule 1
EC Certificate: <i>If self-declared add "N/A Self-Declared"</i>	Number: N/A Self-Declared	Issue Date: N/A Self-Declared
Quality Management Certificate:	Number: FM 536366	Effective Date: 29 May 2020
Notified Body:	BSI Group The Netherlands B.V.	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Telephone: +31 20 346 0780 Notified Body Number: 2797
<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 Directive 93/42/EEC as amended by directive 2007/47/EC, and its relevant transposition into national laws of the member states into which the devices are placed. We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.</p>		
<p>Signed for on behalf of TIDI Products LLC, by Regulatory Affairs Manager; Amanda Altan, in Neenah Wisconsin.</p>		
Name of Authorized Person	Title	Date
Approval: 	Regulatory Affairs Manager	12 April 2021



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Product Model Numbers, GMDN, and Description to which this declaration applies.		
Model Numbers	GMDN	Description
1100DTS-NSB	56631	OEM Bulk Pack Tape Strip
2200NUZA-NSB	56631	Extra small securement device with zinc oxide adhesive
2800FCS-NSB	56631	Foley Catheter Securement Device
3200S-NSB	56631	Small Universal Securement Device for lines and tubes sized 4.5 -13.5 fr
3300M-NSB	56631	Medium Universal Securement Device for lines and tubes sized 9-24 fr
3300MART-NSB	56631	Arterial and Peripheral IV Catheter Securement Device
3300MART-NSB5	56631	Arterial and Peripheral IV Catheter Securement Device
3300MEPI-NSB	56631	Epidural Catheter Securement Device
3300MIV-NSB	56631	Peripheral IV & Arterial Catheter Securement Device
3300MIV-NSB5	56631	Peripheral IV & Arterial Catheter Securement Device
3300MWA-NSB	56631	Medium Universal Securement Device with wide silicone adhesive area
3300MW-NSB	56631	Medium Universal Securement with wide silicone adhesive area
3301MCS-HL-NSB	56631	Medium Catheter Securement for PICC/CVC Applications
3301MCS-LT-NSB	56631	Medium Catheter Securement for Stingray® Connector
3303MCS-TA-NSB	56631	Universal Securement Device
3304MCS-BA-NSB	56631	Universal Securement Device
3400L-NSB	56631	Large Universal Securement Device for lines and tubes sized 16-40 fr
3400LFC-NSB	57982	Foley Catheter Securement Device for 2 & 3 way Foley Catheters sized 12-30 fr
3500DFN-NSB	56631	Dialysis Fistula Needle Securement Device
3601CVC-NSB	56631	Universal CVC Securement Device
3601CVC-NSB5	56631	Universal CVC Securement Device
3604MCS-TA-NSB	56631	Catheter Fixation for Arrow® PICC/CVC
5804.04-NSB	56631	PICC Fixation
5804.08-NSB	56631	Paediatric PICC Fixation Device
5804.10-NSB	56631	MaxFlo PICC Fixation
MCGLPICC-NSB	56631	Catheter Fixation for MEDCOMP® PICC/CVC
ZL2003MW-NSB	56631	Z lok OEM Bulk Package
03.06.70.10	56631	Medium sized Securement Device
01.60.70.10	57982	Catheter Securement for Bard® PICC & CVC
6554	57982	Posey pulse oximeter probe wrap
8197S	57982	Posey Foam Trach ties - Small
8197M	57982	Posey Foam Trach ties - Medium
8197L	57982	Posey Foam Trach ties - Large
8197XL	57982	Posey Foam Trach ties – Extra large
81975	57982	Posey Foam Trach ties
8141	56631	Posey IV Shield



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Glossary of Global Medical Device Nomenclature (GMDN) Terms

GMDN	Term
56631	Wearable percutaneous catheter/tube holder
57982	Urinary catheter holder

The products to which this declaration relates are developed and manufactured in conformity with the following standard(s).

Safety Standard	Title
ISO 13485	Quality Management System
ISO 14971	Standard for Medical Devices - Application of Risk Management
ISO 10993	Biological Evaluation of Medical Devices