



# Declaration of Conformity DC0001 Rev. 14

<b>Manufacturer and Contact:</b>	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA	Management Representative: Amanda Altan, Manager, Regulatory Affairs
<b>Authorized Representative:</b>	MDSS GmbH Schiffgraben 41 30175 Hannover, Germany	Telephone (+49) 511 6262 8630
<b>Conformity Assessment Procedure:</b>	Annex V and VII of MDD 93/42/EEC Council Directive as amended by directive 2007/47/EC	
<b>Technical File No.:</b>	TF-0020: TIDI Products Grip-Lok Securement	
<b>Product Scope:</b>	Grip-Lok adhesive skin attachment and securement device for anchoring catheters, tubes, and lines.	
<b>Model Numbers:</b>	See following page(s) for model numbers, GMDNs, and descriptions.	
<b>Device Classification:</b>	Class 1 Sterile	Rule 1
<b>EC Certificate:</b>	Number: CE 620856	Issue Date: 2020-03-10
<b>Quality Management Certificate:</b>	Number: FM 536366	Effective Date: 2020-05-29
<b>Notified Body:</b>	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>		
<b>Signed for on behalf of TIDI Products LLC, by:</b> <b>Javorka Spalevic, Sr. RA Specialist in Lincolnshire, IL.</b>		
<b>Name of Authorized Person</b>	<b>Title</b>	<b>Date</b>
<b>Approval:</b> 	Sr. RA Specialist	02/15/2023



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Product Model Numbers, GMDN, and Description to which this declaration applies		
Model Numbers	GMDN	Description
2100ANG	36053	Small Nasogastric Securement Device, For lines and tubes sized 4.5 - 19 Fr
2100NGH	56631	Small Nasogastric Hydrocolloid Securement Device, For lines and tubes sized 4.5 - 19 Fr
2200NUZA	56631	Extra Small Securement Device with Zinc-Oxide Adhesive
3200S	56631	Small Universal Securement Device, For lines and tubes sized 4.5-13.5 Fr
3300M	56631	Medium Universal Securement Device, For lines and tubes sized 9 - 24 Fr
3300MART	56631	Medium Peripheral IV and Arterial Catheter Securement Device
3300MART-KIT-2	56631	Medium Peripheral IV and Arterial Catheter Securement Device and Dressing Kit
3300MEPI	56631	Medium Universal Catheter Securement Device
3300MIV	56631	Medium Peripheral IV and Arterial Catheter Securement Device
3300MWA	56631	Medium Universal Securement with Wide Silicone Adhesive Area
3300MW-TA-3	56631	Grip-Lok®, Medium Wide Std Adhesive for Arrow
3301MCS-BD	56631	Medium Securement Device for the BD Arterial Cannula with FloSwitch™
3301MCS-HL	56631	Medium Catheter Securement for PICC/CVC Applications
3303MCS-TA	56631	Medium Catheter Securement Device for Arrow® PICC/CVC
3304MCS-BA	56631	Medium Catheter Securement Device for Bard® PICC and CVC
3306MCS-NA	56631	Medium Catheter Securement Device for Navilyst Medical Xcela® PICC
3308MCS-MC	56631	Medium Catheter Securement Device for Medcomp® Dialysis Catheter
3400L	56631	Large Universal Securement Device, For lines and tubes 16 - 40 Fr
3400LFC	57982	Large Foley Catheter Securement Device, For 2 & 3 way Foley Catheters Sized 8 - 30 Fr
3401LNG	36053	Large Nasogastric Tube Securement Device
3500DFN	56631	Dialysis Fistula Needle Securement
3600PFC	57982	Small Foley Catheter Securement Device, For 2 & 3 Way Foley Catheters Sized 8 - 30 Fr
3601CVC	56631	Medium Universal PICC and CVC Securement Device, For lines and tubes sized 14 - 40 Fr
3604MCS-TA-1	56631	Catheter Fixation for Arrow® PICC/CVC
3300MIV-KIT-2	56631	Medium Peripheral IV and Arterial Catheter Securement Device and Dressing Kit
A20100090	56631	M- Fixx™
MCGLPICC	56631	Catheter Fixation for MEDCOMP®PICC/CVC



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04439010	56631	Picc-Cel Grip-Lok® Securement Device for Celsite PICC-Cel Catheters
3200S-10PK	56631	Small Universal Securement Device, For lines and tubes sized 4.5-13.5 Fr
3300M-10PK	56631	Medium Universal Securement Device, For lines and tubes sized 9-24 Fr
3400L-10PK	56631	Large Universal Securement Device, For lines and tubes 16-40 Fr
3400LFC-10PK	57982	Large Foley Catheter Securement Device, For 2 & 3 way Foley Catheters sized 8 - 30 Fr
3309MCS-TA-2	56631	Catheter Fixation for Arrow® PICC/ CVC
3360MWA	56631	Universal Catheter Securement with Aplicare® P-1010 Skin Prep Pad
3460L	56631	Universal Securement Device with 2 Aplicare® P-1010 Skin Prep Pads for lines and tubes sized 6-13 mm in diameter
3460LFC	57982	Foley Catheter Securement Device 2 Aplicare® P-1010 Skin Prep Pads for 2 & 3 way Foley Catheters sized 12-30 Fr.

## 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

## 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