



Declaration of Conformity DC0041 Rev. 03

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-0022: TIDI Products Medical Barriers Family	
Product Identification:	Non-Sterile Equipment Covers & Non-Sterile Urology Drain Bags	
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate	
Basic UDI-DI, EMDN codes and Intended purpose:	<p>The medical barriers are intended to protect the equipment it covers. The Urology drain bags are intended for use as accessories to an urological table for fluid containment.</p> <p>Basic UDI-DI for medical barriers:</p> <ul style="list-style-type: none"> • General - non-sterile 0618125TF-0022-BWY • Urology Drain Bags 0618125TF-0022-FX8 <p>EMDN code for medical barriers:</p> <ul style="list-style-type: none"> • T030102 – Cover Sheaths, Instruments and Equipment 	
Device Classification/Rule:	Risk Class I	Rule 1
Reference to Common Specifications:	N/A	
EC Certificate:	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
Quality Management Certificate:	Number: MD 552719	Effective Date: 2020-08-16
Notified Body Information For QMS:	BSI Group the Netherlands B.V. Say Building John M. Keynesplein 9	



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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 Neenah, WI.

Name of Authorized Person:	Title:	Date:
Approval: <i>Javoroka Spalevic</i>	Sr. Regulatory Affairs Specialist	08 Dec 2021

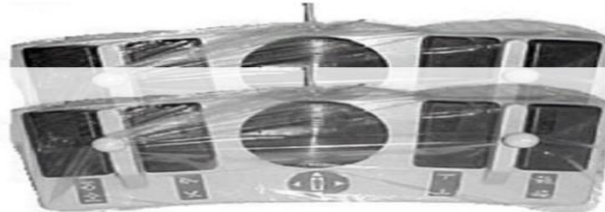




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Model Number (REF)	Product Name	GMDN	UDI-DI
28489	Breast Shield Cover with Flap 10" x 21"	12535	00618125184002
00-900940-01-OEC, E9100AZ (20780)	All OEC UroView/ Urofast Systems Disposable Collection Bag 5 gallon/19 liter	61677	00618125184019
5402 N/S	Mini C-Arm Kit	12535	00618125101641
5403 N/S	Mini C-Arm Drape	12535	00618125101658
CFI-652 N/S	Band Bag 30" x 14.50"	12535	00618125101870
CFI-654 N/S	Band Bag 36" x 20"	12535	00618125101887
CFI-657 N/S	Clear Band Bag 36"x 36"	12535	00618125141272
CFI-657T N/S	Clear Band Bag w/Tape 36"x 36"	12535	00618125167470
CFI-664 N/S	Band Bag 20" x 15"	12535	00618125102181
CFI-689 N/S	Clear Drape 23" x 32"	12535	00618125102204
CFI-699T N/S	Clear Drape w/Tape 30" x 30"	12535	00618125114252
CFI-702 N/S	Set Up Cover 44" x 70"	12535	00618125102211
CFI-704 N/S	Slush Drape 54" x 54"	12535	00618125102211
CFI-733 N/S	Clear Dome Bag 24"	12535	00618125102228
CFI-733-B N/S	Blue Dome Bag 24"	12535	00618125102259
CFI-753F N/S	Band Bag 28" x 14"	12535	00618125102266
CFI-786 N/S	Dome Bag 14"	12535	00618125102273
CFI-821 N/S	Dome Bag 22"	12535	00618125102310
CFI-821FL N/S	Dome Bag 22"	12535	00618125102327
CFI-835 N/S	Band Bag 36" x 28"	12535	00618125102334
CFI-911 N/S	Dome Bag 18"	12535	00618125102341
9032	Protective Table Cover	12535	00618125102365
9053	CT Bore Drape	12535	00618125102402
C000-0492 (22918)	Accessory Footswitch Cover 24" X 20"	12535	00618125155699
5434 N/S	C-Arm Drape with Tie Straps	12535	00618125102488
CFI-956 N/S	Cassette Cover 14" x 17"	12535	00618125102495
CFI-959 N/S	X-Ray Cassette Cover 24" x 24"	12535	00618125140848
284156 (24701)	DePuy Synthes Footswitch Cover 24" x 14"	12535	00618125160662
284163 (24995)	DePuy Synthes Footswitch Cover 12" x 12"	12535	00618125175529
5406	Footswitch Cover 17" x 15"	12535	00618125140046
5421	Wide Footswitch Cover 24" x 20"	12535	00618125139880
5422	Wide Footswitch Cover 36" x 20"	12535	00618125142194
CFI-707 N/S	Footswitch Cover 12" x 8"	12535	00618125140633
CFI-748 N/S	Foot Switch Cover 20" x 12"	12535	00618125143535
CFI-961 N/S	Foot switch Cover 14" x 30"	12535	00618125143641
CFI-963 N/S	Foot Switch Cover 24" x 20"	12535	00618125143658
CFI-964 N/S	Footswitch Cover 30" x 30"	12535	00618125143665
00-900410-02-OEC, E9100AD (20764)	Gray Footswitch Cover All OEC Systems	12535	00618125152193
00-900941-01-OEC, E9100BC (20763)	OEC UroView 2600 Disposable Wide Footswitch Cover	12535	00618125112371
00-902099-01, E9100BJ (21185)	OEC UroView 2800 Disposable Wide Footswitch Cover	12535	00618125152230

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Model Number (REF)	Product Name	GMDN	UDI-DI
5300 N/S	Uro-Catcher Bag	61677	00618125141111
5313 N/S	Uro-Catcher Drain Bag	61677	00618125141128
5442 N/S	Urology Drain Bag	61677	00618125140985
5477	6" Extender Hose with Adapter	61677	00618125142989
5010	Contain Drain Urology Drain Collection Bag	61677	00618125139989
C000-0612A (25340)	Urology Drain Collection Unit	61677	00618125155705
PM-1052-SGH (29531)	UroFunnel Bag	61677	00618125167395
PM-1052 (29532)	UroFunnel Bag	61677	00618125160990
PM-1050-2 (29702)	Poly UroFunnel Bag	61677	00618125160969
C000-1111 (32586)	Urology Drain Bag	61677	00618125155712
9501000 (30415)	Urology Drain Bag	61677	00618125160921
31319	Urology Drain Bag	61677	00618125151905
PM-1050-2-10 (31432)	Poly UroFunnel Bag	61677	00618125160976
3075-8000-00000-000 (32065)	G2 Drain Bag	61677	00618125167975
PM-10528 (33316)	UroPro UroFunnel Bag	61677	00618125190546

Product Name	Photo (if appropriate)
Wide Footswitch Cover 36" x 20"	
Band Bag 20" x 15"	
OEC UroView/Urofast Systems Disposable Collection Bag 5 gallon/19 liter (20780)	



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GMDN	Term
12535	Medical equipment drape, single use
61677	Urological Fluid Funnel, non-sterile

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