EU/UK/AU/CH Declaration of Conformity
DC0041 Rev. 14

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

Manufacturer Information:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA SRN: US-MF-000012287
Person Responsible for Regulatory Compliance (PRRC):	Chris Rahn, VP Quality & Regulatory
European Union (EU) Authorized Representative Contact Information:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany Phone: (+49) 511 6262 8630 SRN: DE-AR-000005430
United Kingdom (UK) Responsible Person Contact Information:	Emergo Consulting (UK) Limited c/o Cr360 UL International Compass House, Vision Park Histon Cambridge CB24 9BZ, United Kingdom Phone: +44(0) 1223 772 671
Swiss (CH) Authorized Representative Contact Information:	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland CHRN: CHRN-AR-20001035.
Product identification:	Non-Sterile Equipment Covers & Non-Sterile Urology Drain Bags
Technical File No.:	TF-0022: TIDI Products Medical Barriers Family
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photos, where appropriate
EU Legislation and 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.
UK Legislation and Conformity Assessment Procedure:	UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). Conformity to Part II of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002).
Australia (AU) Legislation and Conformity Assessment Procedure:	Clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002
CH Legislation and 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.
Intended purpose:	The medical barriers are intended to protect the equipment it covers.

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	The Urology drain bags are intended for use as accessories to an urological table for fluid containment.	
EMDN Code:	EMDN code for medical barriers and urology drain bags: • T030102 – Cover Sheaths, Instruments and Equipment • A060303 – Urine collection systems and bags, single use	
Basic UDI-DI:	Basic UDI-DI for medical barriers and urology drain bags: • General - non-sterile 0618125TF-0022-BWY • Urology Drain Bags 0618125TF-0022-FX8	
Device Classification/ Rule in EU/CH:	Risk Class I	Rule 1
Device Classification/ Rule in UK:	Risk Class I	Rule 1
Device Classification/ Rule in Australia (AU):	Risk Class I	Rule 2.1
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	NA	
EC Certificate:	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
UKCA Certificate:	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 29 May 2023
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 29 May 2023
Notified Body for QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands NB No. 2797	
Notified Body for EU Conformity Assessment: *(if applicable)*	NA	
Approved Body for UK Conformity Assessment*: (if applicable*)	NA	

:For European Union (Non-sterile products)

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

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designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

For United Kingdom:

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 UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).). We explicitly designate Emergo Consulting (UK) Limited to act as our sole Responsible Person in the UK for the above indicated products.

For Australia (Non-sterile products):

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 each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, and the classification rules before being supplied under clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods Administration Medical Device Regulation 2002.

For Switzerland:

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 applicable parts of the MedDO. These are class I medical devices that declare conformity to Regulation (EU) 2017/745 (MDR). We explicitly designate MDSS CH GmbH to act as our sole Authorised Representative in Switzerland for the above indicated products.

Signed on behalf of TIDI Products LLC, in Neenah, WI. 54956

Name of TIDI Representative; Javorka Spalevic	**Title, Function**	**Date**
Approval: Javorka Spalevic	**Approval:** Regulatory Affairs Compliance Manager	03/19/2025

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies

Model Number (REF)	Product Name	GMDN	UDI-DI
C000-0492 (22918)	Accessory Cover	12535	00618125155699
CFI-956 N/S	X-Ray Cassette Cover	12535	00618125102495
CFI-959 N/S	X-Ray Cassette Cover	12535	00618125140848
5406	Footswitch Cover	12535	00618125140046
5421	Wide Footswitch Cover	12535	00618125139880
00-900410-02-OEC, E9100AD (20764)	Gray Footswitch Cover All OEC® System	12535	00618125152193
00-900941-01-OEC, E9100BC (20783)	OEC UroView® 2600, Disposable Wide Footswitch Cover	12535	00618125112371

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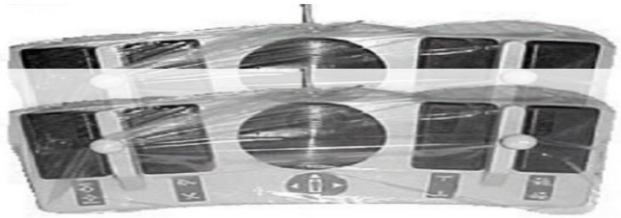
Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
00-900940-01-OEC, E9100AZ (20780)	All OEC UroView®/Urofast Systems Disposable Collection Bag 5 gallon/19 liter	61677	00618125184019
00-902099-01, E9100BJ (21185)	OEC UroView® 2800, Disposable Wide Footswitch Cover	12535	00618125152230
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
C000-1111 (32586)	Urology Drain Bag	61677	00618125155712
3075-8000-00000-000 (32065)	G2 Drain Bag	61677	00618125167975
31780 N/S (BF459)	Urology Drain Bag	61677	00618125192274

Product Name	Photo (if appropriate)
Wide Footswitch Cover (5421)	
All OEC UroView®/Urofast Systems Disposable Collection Bag 5 gallon/19 liter (20780)	

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
12535	Medical equipment/instrument drape, single-use
61677	Urological Fluid Funnel