EU/UK/CH Declaration of Conformity
DC0078 Rev. 03

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:	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 photo, where appropriate
EU Legislation and Conformity Assessment Procedure:	Annex V and VII of MDD 93/42/EEC Council Directive as amended by directive 2007/47/EC
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 V (as modified by Part II of Schedule 2A to the UK MDR 2002).
Australia (AU) Legislation and Conformity Assessment Procedure:	NA – not marketing in AU
CH Legislation and Conformity Assessment Procedure:	Annex V and VII of MDD 93/42/EEC Council Directive as amended by directive 2007/47/EC

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Intended purpose:	The Urology drain bags are intended for use as accessories to a urological table for fluid containment.	
EMDN Code:	EMDN code for urology drain bags: • A060303 -Urine collection systems and bags, single use	
Basic UDI-DI:	Basic UDI-DI for urology drain bags: • Urology Drain Bags 0618125TF-0022-FX8	
Device Classification/ Rule in EU/CH:	Class 1 Sterile	Rule 1
Device Classification/ Rule in UK:	Class 1 Sterile	Rule 1
Device Classification/ Rule in Australia (AU):	NA	NA
Australian Client ID No.	NA	
Reference to Common Specifications:	N/A	
EC Certificate:	Number: CE 620856	Issue Date: 2020-03-10
UKCA Certificate:	Number: UKCA 757280	Issue Date: 2021-12-07
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 Notified Body Number: 2797	
Notified Body for EU Conformity Assessment:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
Approved Body for UK Conformity Assessment*:*	BSI UK Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, United Kingdom MK5 8PP Approved Body Number 0086	

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For European Union (Sterile devices):

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.

For United Kingdom (Sterile devices):

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 Switzerland (Sterile devices):

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 Is medical devices that declare conformity to Directive 93/42/EEC. We explicitly designate MDSS CH GmbH to act as our sole Authorised Representative in Switzerland for the above indicated products.

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

Name of TIDI Representative; Javorka Spalevic	**Title, Function**	**Date**
Approval: 	**Approval:** Regulatory Product Manager	01/24/2024

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies.			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
00-900885-01-OEC, E9100BB (20782)	OEC UroView® 2600/2800 Disposable Drainbag with Hose	61677	00618125112364
00-901761-01,E9100BH (21184)	OEC Uroview® 2800 Disposable Covers Kit	61677	00618125152223
5300	Urology Drain Bag	61677	00618125139996
5313	Urology Drain Bag	61677	00618125140015
5416	Urology Drain Bag Kit	61677	00618125140084
5419	Urology Drain Bag with Table Flap	61677	00618125140091
C000-0593 (25217)	Urology Drain Bag	61677	00618125155682
CF507505 (25429)	Urology Drain Bag for Siemens UROSKOP Access	61677	00618125157587
26064	Urology Drain Bag	61677	00618125151967
5442SCL (26326)	Urology Drain Bag for Siemens UROSKOP Access, OMNIA/ or OMNIA MAX	61677	00618125157570

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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**
5442	Urology Drain Bag Siemens UROSKP Access	61677	00618125140138

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
61677	Urological Fluid Funnel

Product Name	Photo (if appropriate)
OEC Uroview® 2800 Disposable Covers Kit (21184)