



## EU/UK/CH Declaration of Conformity DC0078 Rev. 07

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

<b>Manufacturer Information:</b>	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 , USA SRN: US-MF-000012287
<b>Person Responsible for Regulatory Compliance (PRRC):</b>	Chris Rahn, VP, Quality & Regulatory
<b>European Union (EU) Authorized Representative Contact Information:</b>	MDSS GmbH Schiffgraben 41 30175 Hannover Germany Phone : (+49) 511 6262 8630 SRN: DE-AR-000005430
<b>United Kingdom (UK) Responsible Person Contact Information:</b>	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
<b>Swiss (CH) Authorized Representative Contact Information:</b>	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland CHRN: CHRN-AR-20001035
<b>Product identification:</b>	Urology Drain Bags
<b>Technical File No.:</b>	TF-0022: TIDI Products Medical Barriers Family
<b>Product Model Numbers:</b>	See the following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate
<b>EU Legislation and Conformity Assessment Procedure:</b>	Medical Device Regulation (EU) 2017/745, Annex IX Chapter I and III. Annex IX: Conformity Assessment based on a quality management system and on assessment of technical documentation of Medical Device Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.
<b>UK Legislation and Conformity Assessment Procedure:</b>	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).
<b>Australia (AU) Legislation and Conformity Assessment Procedure:</b>	NA – not marketing in AU
<b>CH Legislation and Conformity Assessment Procedure:</b>	Medical Device Regulation (EU) 2017/745, Annex IX Chapter I and III.



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<b>Intended purpose:</b>	The Urology drain bags are intended for use as accessories to a urological table for fluid containment.	
<b>EMDN Code:</b>	EMDN code for urology drain bags: <ul style="list-style-type: none"> <li>A060303 -Urine collection systems and bags, single use</li> </ul>	
<b>Basic UDI-DI:</b>	Basic UDI-DI for urology drain bags: <ul style="list-style-type: none"> <li>Urology Drain Bags 0618125TF-0022-FX8</li> </ul>	
<b>Device Classification/ Rule in EU/CH:</b>	Class 1 Sterile	Rule 1
<b>Device Classification/ Rule in UK:</b>	Class 1 Sterile	Rule 1
<b>Device Classification/ Rule in Australia (AU):</b>	NA	NA
<b>Australian Client ID No.</b>	NA	
<b>Reference to Common Specifications:</b>	N/A	
<b>MDR Certificate:</b>	Number: MDR 766741	Issue Date: 2024-03-07
<b>UKCA Certificate:</b>	Number: UKCA 757280	Issue Date: 2021-12-07
<b>Quality Management Certificate - ISO 13485</b>	Number: FM 536366	Effective Date: 2023-05-29
<b>MDSAP Certificate</b>	Number: MDSAP 703786	Effective Date: 2023-05-29
<b>Notified Body for QMS:</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
<b>Notified Body for EU Conformity Assessment:</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
<b>Approved Body for UK Conformity Assessment:</b>	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 Medical Device Regulation (EU) 2017/745. 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 (SI 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 Medical Device Regulation 2017/745. We explicitly designate MDSS CH GmbH to act as our sole Authorized Representative in Switzerland for the above indicated products.

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

<b>Name of TIDI Representative;</b> Javorka Spalevic	<b>Title, Function</b>	<b>Date</b>
<b>Approval:</b>	<b>Approval:</b> Regulatory Affairs Compliance Manager	

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	61677	00618125157587
26064	Urology Drain Bag	61677	00618125151967
5442SCL (26326)	Urology Drain Bag	61677	00618125157570
5442	Urology Drain Bag	61677	00618125140138
31780 (BF458)	Urology Drain Bag	61677	00618125192267

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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)	