



EU/UK/AU/CH Declaration of Conformity DC0016 Rev. 26

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, Senior Director 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:	Sterile Equipment Covers, Patient Drapes and 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:	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 V and VII of MDD 93/42/EEC Council Directive as amended by directive 2007/47/EC



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Intended purpose:	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.	
EMDN Code:	EMDN code for medical barriers: T030102 – Cover Sheaths, Instruments and Equipment	
Basic UDI-DI:	Basic UDI-DI for medical barriers: <ul style="list-style-type: none"> • Urology Drain Bags 0618125TF-0022-FX8 • General sterile 0618125TF-0022-AWW • Zero Gravity drapes 0618125TF-0022-CX2 • Sterile-Z drapes 0618125TF-0022-DX4 • Patient contacting 0618125TF-0022-EX6 	
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):	Class 1 Sterile	Rule 2.1
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
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,	



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United Kingdom MK5 8PP
Approved Body Number 0086

For European Union (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 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:

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 (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 declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures 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 Is medical devices that declare conformity to Directive 93/42/EEC. We explicitly designate MDSS CH GmbH to act as our sole Authorized 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: <i>Javorka Spalevic</i>	Approval: Sr. RA Specialist	07/10/2023



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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
5523	C-Armor Drape	12535	00618125140152
5536	C-Armor & I.I. Drape Kit	12535	00618125140169
5402	Mini C-Arm Kit	12535	00618125140022
5403	Mini C-Arm Drape 48" x 84"	12535	00618125140039
5411	Image Intensifier/ X-Ray Tube Cover 30" x 32" with Cut Corners & Rubber Band	12535	00618125140053
5412	Image Intensifier/X-Ray Tube Cover 36" x 36" with Rubber Band	12535	00618125140060
5414	C-Arm Drape with Rubber Band	12535	00618125140077
5420	Hand Control Cover 5" x 10"	12535	00618125142187
5423	Mini C-Arm Drape	12535	00618125139897
5425	Dome Bag 15" Depth	12535	00618125142217
5427	C-Arm Drape with Clips	12535	00618125142224
5429	C-Arm Drape Kit	12535	00618125140107
5434	C-Arm Drape with Tie Straps	12535	00618125140121
5460	C-Arm Drape Kit	12535	00618125142873
5464	C-Arm Drape Kit	12535	00618125142279
32378	Scatter Guard Drape Kit	12535	00618125143856
29412	9600/9800/9900 Consumables Pack 12" I.I.	12535	00618125155552
CFI-600	Blue Band Bag 36" x 28"	12535	00618125140329
CFI-601	Blue Band Bag with Cut Corners 36" x 18"	12535	00618125142569
CFI-6030	Rounded Band Bag 30" (48" x 34")	12535	00618125140350
CFI-651	Band Bag 20" x 20"	12535	00618125142583
CFI-653CC	Band Bag with Cut Corners 30" x 17"	12535	00618125143467
CFI-654	Band Bag 26" x 20"	12535	00618125140404
CFI-655	Band Bag 36" x 30"	12535	00618125140428
CFI-657	Band Bag 36" x 36"	12535	00618125141265
CFI-661	Band Bag 30" x 30"	12535	00618125140442
CFI-667	Band Bag 30" x 36"	12535	00618125142590
CFI-668	Band Bag 42" x 36"	12535	00618125140473
CFI-690	Band Bag 48" x 36"	12535	00618125143511
CFI-733	Dome Bag 24" Depth	12535	00618125140657
CFI-756	Dome Bag 27" Depth	12535	00618125142651
CFI-761	Band Bag 40" x 30"	12535	00618125141364
CFI-762	Dome Bag 20" Depth	12535	00618125143924
CFI-821	Dome Bag 22" Depth	12535	00618125142668
CFI-827	Band Bag 40" x 40"	12535	00618125142675
00-901917-01, E9100BF (20475)	OEC Miniview 6800 C-Arm Disposable Cover	12535	00618125152063



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Model Number (REF)	Product Name	GMDN	UDI-DI
00-901918-01-OEC, E9100BE (20493)	OEC Miniview 6800 C-Arm Disposable Cover Kit	12535	00618125152056
00-900974-01, E9100AA (20761)	OEC MiniView 6600 Disposable Covers Kit	12535	00618125152087
00-901391-01, E9100AE (20765)	OEC MiniView 6600 C-Arm Disposable C-Arm Cover 40-inch x 84 inch/ 102 cm x 213 cm	12535	00618125152094
00-901501-01-OEC, E9100AG (20767)	OEC 8800/0600/9800/9900 C-Arms with 9-inch I.I. Disposable Covers Kit	12535	00618125152209
00-901588-01-OEC, E9100AH (20768)	OEC 8800/9600/9800/9900 C-Arms with 12-inch I.I. Disposable Covers Kit	12535	00618125152216
00-900493-03, E9100AJ (20769)	OEC 8800/9600/9800/9900 C-Arms with 9-inch I.I. Disposable Cover, X-Ray Tube or I.I. 30-inch x 32 inch/ 76 cm x 81 cm	12535	00618125152384
00-901169-01-OEC, E9100AK (20770)	OEC 8800/9600/9800/9900 C-Arms with 12-inch I.I. Disposable Cover, X-Ray Tube or I.I. 36-inch x 36 inch/ 91 cm x 91cm	12535	00618125168026
00-901268-01, E9100AM (20772)	OEC 7600/7700/8800/9600/9800/9900 C-Arms Disposable Steriquick Cover	12535	00618125160587
00-900943-01, E9100AP (20774)	OEC 9000/9400/8800/9600/9800/9900 C-Arms Disposable Half C-Arm Covers 36-inch x 80 inch / 91 cm x 203 cm	12535	00618125161959
00-902753-01 (24808)	OEC 9800 MD C-Arm with 9-inch I.I. Disposable Covers Kit	12535	00618125152247
00-902754-01 (24810)	OEC 9800 MD C-Arm with 12 Inch I.I. Disposable Covers Kit	12535	00618125158287
9731831 (24881)	Drape AxiEm Emitter	12535	00618125152032
9732315 (24993)	Bag Mouse Sterile	12535	00618125152360
9732571 (25847)	Drape, AxiEM Cranial	12535	00618125160730
CF513601 (26929)	C-Arm Drape Kit	12535	00618125160594
CF509617 (26968)	C-Arm Drape Kit	12535	00618125163960
29850	Sterile Display Bag	12535	00618125167937
E7009CA (30351)	Sterile Drape for Ge Innova 2100 X-Ray System	12535	00618125152438
E7009CB (30352)	Sterile Drape for GE Innova 3100 X-Ray System	12535	00618125152445
E7009CC (30353)	Sterile Drape for GE Innova 4100 X-Ray System	12535	00618125152452
E7009CD (30727)	Kit for GE Innova 2100 X-Ray System	12535	00618125155262
E7009CE (30728)	Drape for GE Innova 3100 X-Ray System	12535	00618125158270
E7009CF (30729)	Drape for GE Innova 4100 X-Ray System	12535	00618125152261
E7009HA (30801)	Sterile Mobile XR Tube Drape	12535	00618125155279
E7009HB (30802)	Sterile Flash pad Detector Drape	12535	00618125152469



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Model Number (REF)	Product Name	GMDN	UDI-DI
131179 (30877)	Disposable Cover Set	12535	00618125175352
131180 (30880)	Disposable Cover Set	12535	00618125161041
131181 (30882)	Disposable Cover Set	12535	00618125161058
131182 (30883)	Disposable Cover Set	12535	00618125175369
131183 (30885)	Disposable Cover for Vision Center/ Solo Center/ Remote Vision Center	12535	00618125167036
131150 (31599)	Disposable Cover Includes: Position Control Center Drape	12535	00618125161065
131184 (30896)	Disposable Cover for Image Intensifier Housing	12535	00618125167043
200-700-00 (33442)	Sterile DOC Cover 9" x 96"	12535	00618125188635
5456276 (31410)	Desk Top Drape	12535	00618125152476
131924 (33196)	Disposable Cover Set	12535	00618125182121
5999777 (31882)	C-Arm Drape Kit with Plate Protector and Foot Switch Cover	12535	00618125152308
5999198 (31883)	C-Arm Drape Kit with Skin Spacer, Plate Protector and Foot Switch Cover	12535	00618125152179
5999784 (32860)	C-Arm Half Drape	12535	00618125152049
5999197 (32862)	C-Arm Drape Kit with Skin Spacer and Foot Switch Cover	12535	00618125152117
5999417 (32863)	C-Arm Drape	12535	00618125152124
131925 (33195)	Disposable Cover Set	12535	00618125182138
5767882 (34008)	Drape, Monitor, 4K	12535	00618125183852
E7009AG (20862F)	Clear Dome Bag 27"	12535	00618125160488
E7009BD (20866F)	Clear Band Bag, 30" x 20"	12535	00618125160549
ZGD20WA-LOOP	Zero-Gravity Equipment Cover	12535	00618125142965
5565	TIDIShield O-Arm Cover	12535	00618125140183
5574	STERILE-Z Patient Drapes	12535	00618125140213
5575	STERILE-Z Back Table Cover	12535	00618125140220
5575-XL	STERILE-Z Back Table Cover- XL	12535	00618125141166
5582	STERILE-Z Mayo Stand Cover	12535	00618125142422
CFI-705	X-Ray Cassette Cover 24" x 36"	12535	00618125140602
CFI-959	X-Ray Cassette Cover 24" x 24"	12535	00618125140831
5774511 (33306)	OEC Disposables, 12-in Image Intensifier 9800, 9900 & Elite 31 cm CFM	12535	00618125187171
5845455 (33323)	GE OEC Elite 31cm Flat Panel Drape	12535	00618125189274
5845456 (33324)	GE OEC Elite 21cm Flat Panel Drape	12535	00618125189298
5857958 (33326)	OEC Disposables, 31cm Flat Panel CFD OEC One	12535	00618125190041
5845457 (33325)	GE OEC One 21cm Flat Panel Drape	12535	10618125189235



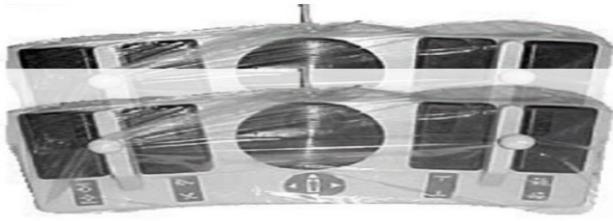


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Model Number (REF)	Product Name	GMDN	UDI-DI
5869312 (33328)	OEC 3D Disposable Drape Kit, Detector and C-arm Only	12535	00618125190102
5871178 (33329)	OEC 3D Disposable Drape Kit, Full System with Accessories	12535	00618125190119
00-900885-01-OEC, E9100BB (20782)	OEC UroView® 2600/2800 Disposable Drainbag with Hose	61676	00618125112364
00-901761-01, E9100BH (21184)	OEC Uroview® 2800 Disposable Covers Kit	61676	00618125152223
00-902864-01 (25601)	OEC® 8800/9600/9800/9900 C-Arms Universal Half Drape With Adhesive Ties	12535	00618125152254
E7009AE (22152)	Sterile Drape-AFM / CFM Pedestal intended For Use With: AFM / CFM Pedestal	12535	00618125152391
5448360 (31332)	Monitor Drape intended for Use With: OEC Elite Monitor	12535	00618125152285
5774510 (33305)	OEC® Disposables, 9-inch Image Intensifier, 9800, 9900 & Elite™ 21cm CFM	12535	00618125187164
5999416 (31041)	C-Arm Drape with Plate Protector Intended For Use With: OEC Elite MiniView	12535	00618125152278
5999781 (32861)	C-Arm Drape Kit and Foot Switch Cover	12535	00618125152100
5537	Lateral C-Arm Drape	12535	00618125176816
32634	Brainlab Disposable Curve Monitor Drape, Drape for 27-inch Brainlab monitors	12535	00618125167425
8849777 (31046)	Kit, OEC MiniView C-Arm with 15cm FPD (Flat Panel Detector) Drape and Foot Switch Cover	12535	00618125190775
8849416 (31047)	OEC MiniView C-Arm with 15cm FPD (Flat Panel Detector) Drape	12535	00618125190812
8849780 (31048)	Kit, OEC MiniView C-Arm 15cm with Worksurface Extension Drape and Foot Switch Cover	12535	00618125190799
8849779 (31049)	OEC MiniView C-Arm 15cm with Worksurface Extension Drape	12535	00618125190751
5300	Urology Drain Bag	61676	00618125139996
5313	Urology Drain Bag	61676	00618125140015
5416	Urology Drain Bag Kit	61676	00618125140084
5419	Urology Drain Bag with Table Flap	61676	00618125140091
6900-44 (22826)	Uro-Catcher Bag	61676	00618125175314
C000-0593 (25217)	Urology Drain Bag	61676	00618125155682
CF507505 (25429)	Urology Drain Bag for Siemens UROSKOP Access	61676	00618125157587
26064	Urology Drain Bag	61676	00618125151967
5442SCL (26326)	Urology Drain Bag for Siemens UROSKOP Access, OMNIA/ or OMNIA MAX	61676	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	61676	00618125140138

Product Name	Photo (if appropriate)
Wide Footswitch Cover	
Band Bag 28" x 14"	
OEC UroView/Urofast Systems Disposable Collection Bag	

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	Term
12535	Medical equipment drape, single use
61676	Urological Fluid Funnel, sterile