



## EU Declaration of Conformity DC0016 Rev. 24

<b>Manufacturer and Contact:</b>	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956, USA	Management Representative: Javorka Spalevic Sr. Regulatory Affairs Specialist
<b>Authorized Representative:</b>	MDSS, Medical Device Safety Service Schiffgraben 41 30175 Hannover, Germany	Telephone: 49 511 62628630
<b>Conformity Assessment Procedure:</b>	Annex V and VII of MDD 93/42/EEC Council Directive as amended by directive 2007/47/EC	
<b>Technical File No.:</b>	TF-0022: TIDI Products Medical Barriers Family	
<b>Product Scope:</b>	Sterile Equipment Covers, Patient Drapes and Urology Drain Bags	
<b>Model Numbers:</b>	See following page(s) for model numbers, GMDNs, and descriptions.	
<b>Device Classification:</b>	Class I sterile	Rule 1
<b>EC Certificate:</b>	Number: CE 620856	Issue Date: 02 April 2015
<b>Quality Management Certificate:</b>	Number: FM 536366	Effective Date: 29 May 2020
<b>Notified Body:</b>	BSI Group The Netherlands B.V.	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Telephone: +31 20 346 0780 Notified Body Number: 2797

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.

**Signed for on behalf of TIDI Products LLC, by the Sr. Regulatory Affairs Specialist  
Javorka Spalevic, in Neenah, WI.**

<b>Name of Authorized Person</b>	<b>Title</b>	<b>Date</b>
<b>Approval:</b> <i>Javorka Spalevic</i>	Sr. Regulatory Affairs Specialist	7/27/2022



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Product Model Numbers, GMDN, and Description to which this declaration applies		
Model Numbers	GMDN	Description
5523	12535	C-Arm Drape
5536	12535	C-Armor & I.I. Drape Kit
5402	12535	Mini C-Arm Kit
5403	12535	Mini C-Arm Drape 48" x 84"
5411	12535	Image Intensifier/ X-Ray Tube Cover 30" x 32" with Cut Corners & Rubber Band
5412	12535	Image Intensifier/X-Ray Tube Cover 36" x 36" with Rubber Band
5413	12535	IR Hand Control Cover 7" x 13"
5414	12535	C-Arm Drape with Rubber Band
5420	12535	Hand Control Cover 5" x 10"
5423	12535	Mini C-Arm Drape
5424	12535	Dome Bag 27" Depth
5425	12535	Dome Bag 15" Depth
5427	12535	C-Arm Drape with Clips
5429	12535	C-Arm Drape Kit
5434	12535	C-Arm Drape with Tie Straps
5460	12535	C-Arm Drape Kit
5461	12535	C-Arm/ Image Intensifier Cover
5464	12535	C-Arm Drape Kit
5499	12535	Wireless Mouse Bag
29655	12535	C-Arm Kit Sterile Per OEC 8800/9600/9800
32378	12535	Scatter Guard Drape Kit
03-3100010 (33438)	12535	Biplanar Drape Kit
29412	12535	9600/9800/9900 Consumables Pack 12" I.I.
CFI-600	12535	Blue Band Bag 36" x 28"
CFI-601	12535	Blue Band Bag with Cut Corners 36" x 18"
CFI-6030	12535	Rounded Band Bag 30" (48" x 34")
CFI-650	12535	Band Bag 12" x 8"
CFI-651	12535	Band Bag 20" x 20"
CFI-653	12535	Band Bag 30" x 17"
CFI-653CC	12535	Band Bag with Cut Corners 30" x 17"
CFI-654	12535	Band Bag 26" x 20"
CFI-655	12535	Band Bag 36" x 30"
CFI-655CC	12535	Band Bag with Cut Corners 36" x 30"
CFI-657	12535	Band Bag 36" x 36"
CFI-661	12535	Band Bag 30" x 30"
CFI-667	12535	Band Bag 30" x 36"
CFI-668	12535	Band Bag 42" x 36"
CFI-690	12535	Band Bag 48" x 36"
CFI-733	12535	Dome Bag 24" Depth



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CFI-739	12535	Blue Band Bag 5" x 7"
CFI-756	12535	Dome Bag 27" Depth
CFI-761	12535	Band Bag 40" x 30"
CFI-762	12535	Dome Bag 20" Depth
CFI-768	12535	Sleeve Cover 10" x 14"
CFI-786	12535	Dome Bag 14" Depth
CFI-788T	12535	Clear Drape with Tape 40" x 40"
CFI-821	12535	Dome Bag 22" Depth
CFI-827	12535	Band Bag 40" x 40"
CFI-879	12535	Band Bag 36" x 40"
CFI-893	12535	Dome Bag 26" Depth
CFI-911	12535	Dome Bag 18" Depth
9024	12535	Disposable Sterile Fluoro Control Cover
9052	12535	Hyper Handle Drape
9054	12535	Fluoroscopy Cover Kit
00-901917-01, E9100BF (20475)	12535	OEC Miniview 6800 C-Arm Disposable Cover
00-901918-01-OEC, E9100BE (20493)	12535	OEC Miniview 6800 C-Arm Disposable Cover Kit
00-900974-01, E9100AA (20761)	12535	OEC MiniView 6600 Disposable Covers Kit
00-901390-01, E9100AB (20762)	12535	OEC MiniView 6600 C-Arm with Gray Footswitch Disposable Covers kit
00-901391-01, E9100AE (20765)	12535	OEC MiniView 6600 C-Arm Disposable C-Arm Cover 40-inch x 84 inch/ 102 cm x 213 cm
00-901501-01-OEC, E9100AG (20767)	12535	OEC 8800/0600/9800/9900 C-Arms with 9-inch I.I. Disposable Covers Kit
00-901588-01-OEC, E9100AH (20768)	12535	OEC 8800/9600/9800/9900 C-Arms with 12-inch I.I. Disposable Covers Kit
00-900493-03, E9100AJ (20769)	12535	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
00-901169-01-OEC, E9100AK (20770)	12535	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
00-901268-01, E9100AM (20772)	12535	OEC 7600/7700/8800/9600/9800/9900 C-Arms Disposable Steriquick Cover
00-900943-01, E9100AP (20774)	12535	OEC 9000/9400/8800/9600/9800/9900 C-Arms Disposable Half C-Arm Covers 36-inch x 80 inch / 91 cm x 203 cm
E7009AH (20863)	12535	Clear Dome Bag, 15"
E7009AJ (20864)	12535	Clear Dome Bag, 9"
E7009BG (20869)	12535	Band Bag Sample Pack
00-902752-01	12535	OEC 9800 MD Table Control Disposable Cover
00-902753-01 (24808)	12535	OEC 9800 MD C-Arm with 9-inch I.I. Disposable Covers Kit



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Model Numbers	GMDN	Description
00-902754-01 (24810)	12535	OEC 9800 MD C-Arm with 12 Inch I.I. Disposable Covers Kit
9731831 (24881)	12535	Drape AxiEm Emitter
9732315 (24993)	12535	Bag Mouse Sterile
925.SBCB	12535	Sterile Bag for All Cylindrical Bumps
9732571 (25847)	12535	Drape, AxiEM Cranial
55706	12535	Fluoro Kit C-Arm Drape
26804 (40-00050-000)	12535	Sterile Drape
CF513601	12535	C-Arm Drape Kit
CF509617	12535	C-Arm Drape Kit
29187	12535	Interface Cover
29850	12535	Sterile Display Bag
E7009CA (30351)	12535	Sterile Drape for Ge Innova 2100 X-Ray System
E7009CB (30352)	12535	Sterile Drape for GE Innova 3100 X-Ray System
E7009CC (30353)	12535	Sterile Drape for GE Innova 4100 X-Ray System
E7009CD (30727)	12535	Kit for GE Innova 2100 X-Ray System
E7009CE (30728)	12535	Drape for GE Innova 3100 X-Ray System
E7009CF (30729)	12535	Drape for GE Innova 4100 X-Ray System
E7009HA (30801)	12535	Sterile Mobile XR Tube Drape
E7009HB (30802)	12535	Sterile Flash pad Detector Drape
131179 (30877)	12535	Disposable Cover Set
131180 (30880)	12535	Disposable Cover Set
131181 (30882)	12535	Disposable Cover Set
131182 (30883)	12535	Disposable Cover Set
131183 (30885)	12535	Disposable Cover for Vision Center/ Solo Center/ Remote Vision Center
131185	12535	Disposable Cover for Detector Housing
131186	12535	Disposable Cover for Detector Housing
131150 (31599)	12535	Disposable Cover Includes: Position Control Center Drape
131184 (30896)	12535	Disposable Cover for Image Intensifier Housing
200-700-00 (33442)	12535	Sterile DOC Cover 9" x 96"
31082	12535	CT Drape
925.TRSB	12535	Sterile Bag, The Ramp
925.AAKWLSB	12535	Sterile Bag, Large Acute/Knee Wedge
5456276 (31410)	12535	Desk Top Drape
131550	12535	Disposable Cover
131924 (33196)	12535	Disposable Cover Set
5999777 (31882)	12535	C-Arm Drape Kit with Plate Protector and Foot Switch Cover



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Model Numbers	GMDN	Description
5999198 (31883)	12535	C-Arm Drape Kit with Skin Spacer, Plate Protector and Foot Switch Cover
19903-40	12535	27 Display Drape
5999784 (32860)	12535	C-Arm Half Drape
5999197 (32862)	12535	C-Arm Drape Kit with Skin Spacer and Foot Switch Cover
5999417 (32863)	12535	C-Arm Drape
5999789 (32864)	12535	C-Arm Drape with Skin Spacer
1000-0100	12535	Mini C-Arm Drape Kit
BAG001	12535	Equipment Cover
131925 (33195)	12535	Disposable Cover Set
5767882 (34008)	12535	Drape, Monitor, 4K
E7009AG (20862F)	12535	Clear Dome Bag 27"
E7009BD (20866F)	12535	Clear Band Bag, 30" x 20"
E7009BE (20867F)	12535	Clear Band Bag, 20" x 16"
E7009BF	12535	Bag, Clear band, 12" x 8"
ZGD20WA-LOOP	12535	Zero-Gravity Equipment Cover
5565	12535	TIDIShield O-Arm Cover
5574	12535	STERILE-Z Patient Drapes
5575	12535	STERILE-Z Back Table Cover
5575-XL	12535	STERILE-Z Back Table Cover- XL
5582	12535	STERILE-Z Mayo Stand Cover
CFI-705	12535	X-Ray Cassette Cover 24" x 36"
CFI-954	12535	X-Ray Cassette Cover 8" x 10"
CFI-956	12535	X-Ray Cassette Cover 14" x 17"
CFI-959	12535	X-Ray Cassette Cover 24" x 24"
CFI-960	12535	X-Ray Cassette Cover 30" x 50"
5774511 (33306)	12535	OEC Disposables, 12-in Image Intensifier 9800, 9900 & Elite 31 cm CFM
CFI-706	12535	Footswitch Cover 12" x 12"
CFI-963	12535	Foot Switch Cover 24" x 20"
CFI-748	12535	Footswitch Cover 20" x 12"
5432	12535	Camera Drape with Perforated Tip 5" x 96"
5433	12535	Camera Drape with Elasticized Blue Tip 7" x 96"
CFI-1504	12535	Camera Cover 7" x 96"
25847	12535	Drape, AxiEM™ Cranial
5845455 (33323)	12535	GE OEC Elite 31cm Flat Panel Drape
5845456 (33324)	12535	GE OEC Elite 21cm Flat Panel Drape
5857958 (33326)	12535	OEC Disposables, 31cm Flat Panel CFD OEC One
5845457 (33325)	12535	GE OEC One 21cm Flat Panel Drape
5869312 (33328)	12535	OEC 3D Disposable Drape Kit, Detector and C-arm Only



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5871178 (33329)	12535	OEC 3D Disposable Drape Kit, Full System with Accessories
00-900885-01-OEC, E9100BB (20782)	61676	OEC UroView® 2600/2800 Disposable Drainbag with Hose
00-901761-01, E9100BH (21184)	61676	OEC Uroview® 2800 Disposable Covers Kit
00-902864-01 (25601)	12535	OEC® 8800/9600/9800/9900 C-Arms Universal Half Drape With Adhesive Ties
E7009AE (22152)	12535	Sterile Drape-AFM / CFM Pedestal intended For Use With: AFM / CFM Pedestal
5448360 (31332)	12535	Monitor Drape intended for Use With: OEC Elite Monitor
5773216 (33304)	12535	Purple C-Bow Drape
5774510 (33305)	12535	OEC® Disposables, 9-inch Image Intensifier, 9800, 9900 & Elite™ 21cm CFM
5791435 (33317)	12535	OEC Disposables, 9-inch Image Intensifier OEC One
5999416 (31041)	12535	C-Arm Drape with Plate Protector Intended For Use With: OEC Elite MiniView
5999781 (32861)	12535	C-Arm Drape Kit and Foot Switch Cover
5999788 (31334)	12535	C-Arm Drape with Skin Spacer and Plate Protector
5537	12535	Lateral C-Arm Drape
32634	12535	Brainlab Disposable Curve Monitor Drape, Drape for 27-inch Brainlab monitors
5300	61676	Urology Drain Bag
5313	61676	Urology Drain Bag
5416	61676	Urology Drain Bag Kit
5419	61676	Urology Drain Bag with Table Flap
EM 5300-10 (26894)	61676	Bag, Uro-Catcher Drain
6900-44 (22826)	61676	Uro-Catcher Bag
C000-0593 (25217)	61676	Urology Drain Bag
CF507505 (25429)	61676	Urology Drain Bag for Siemens UROSKOP Access
26064	61676	Urology Drain Bag
5442SCL (26326)	61676	Urology Drain Bag for Siemens UROSKOP Access, OMNIA/ or OMNIA MAX
5442	61676	Urology Drain Bag Siemens UROSKP Access





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