



## EU/UK/AU/CH Declaration of Conformity DC0016 Rev. 32

**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>	Sterile Equipment Covers, and Patient Drapes
<b>Technical File No.:</b>	TF-0022: TIDI Products Medical Barriers Family
<b>Product Model Numbers:</b>	See 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 (SI 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>	Clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002




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<b>CH Legislation and Conformity Assessment Procedure:</b>	Medical Device Regulation (EU) 2017/745, Annex IX Chapter I and III.									
<b>Intended purpose:</b>	<ul style="list-style-type: none"> <li>The medical barriers are intended to cover equipment to help maintain a sterile field.</li> <li>The Sterile-Z patient drapes are intended for use with surgical patient to help maintain a sterile field.</li> </ul>									
<b>EMDN Code:</b>	EMDN code for medical barriers, and surgical patient drapes: <ul style="list-style-type: none"> <li>T030102 – Cover Sheaths, Instruments and Equipment</li> <li>T020199 Surgical Drapes Other (Sterile Z)</li> </ul>									
<b>Basic UDI-DI:</b>	Basic UDI-DI for medical barriers: <table style="width: 100%; border: none;"> <tr> <td style="padding-left: 20px;">• General sterile</td> <td style="text-align: right;">0618125TF-0022-AWW</td> </tr> <tr> <td style="padding-left: 20px;">• Zero Gravity drapes</td> <td style="text-align: right;">0618125TF-0022-CX2</td> </tr> <tr> <td style="padding-left: 20px;">• Sterile-Z drapes</td> <td style="text-align: right;">0618125TF-0022-DX4</td> </tr> <tr> <td style="padding-left: 20px;">• Patient contacting</td> <td style="text-align: right;">0618125TF-0022-EX6</td> </tr> </table>		• General sterile	0618125TF-0022-AWW	• Zero Gravity drapes	0618125TF-0022-CX2	• Sterile-Z drapes	0618125TF-0022-DX4	• Patient contacting	0618125TF-0022-EX6
• General sterile	0618125TF-0022-AWW									
• Zero Gravity drapes	0618125TF-0022-CX2									
• Sterile-Z drapes	0618125TF-0022-DX4									
• Patient contacting	0618125TF-0022-EX6									
<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>	Class 1 Sterile	Rule 2.1								
<b>Australian Client ID No.</b>	TIDI's AU Client ID No.: 49283									
<b>Reference to Common Specifications:</b>	N/A									
<b>EC Certificate:</b>	Number: MDR 766741	Issue Date: 2023-12-06								
<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.									



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	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	
<b>For European Union (Sterile devices):</b> 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.		
<b>For United Kingdom (Sterile devices):</b> 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.		
<b>For Australia (Sterile devices):</b> 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.		
<b>For Switzerland (Sterile devices):</b> 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.		
<b>Signed for on behalf of TIDI Products LLC, in Neenah WI. 54956</b>		
<b>Name of TIDI Representative; Javorka Spalevic</b>	<b>Title, Function</b>	<b>Date</b>
<b>Approval:</b> 	<b>Approval:</b> Regulatory Product Manager	02/02/2024



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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
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
5464	C-Arm Drape Kit	12535	00618125142279
29412	9600/9800/9900 Consumables Pack 12" I.I.	12535	00618125155552
CFI-600	Blue Band Bag 36" x 28"	12535	00618125140329
CFI-6030	Rounded Band Bag 30" (48" x 34")	12535	00618125140350
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-667	Band Bag 30" x 36"	12535	00618125142590
CFI-668	Band Bag 42" x 36"	12535	00618125140473
CFI-733	Dome Bag 24" Depth	12535	00618125140657
CFI-756	Dome Bag 27" Depth	12535	00618125142651
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
00-901918-01-OEC, E9100BE (20493)	OEC Miniview 6800 C-Arm Disposable Cover Kit	12535	00618125152056
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



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Model Number (REF)	Product Name	GMDN	UDI-DI
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
CF513601 (26929)	C-Arm Drape Kit	12535	00618125160594
CF509617 (26968)	C-Arm Drape Kit	12535	00618125163960
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
E7009CE (30728)	Drape for GE Innova 3100 X-Ray System	12535	00618125158270
E7009CF (30729)	Drape for GE Innova 4100 X-Ray System	12535	00618125152261
E7009HB (30802)	Sterile Flash pad Detector Drape	12535	00618125152469
131180 (30880)	Disposable sterile cover set for C-arm with flat-panel detector max. 31 cm x 31 cm	12535	00618125161041
131181 (30882)	Disposable sterile cover set for C-arm with image intensifier max. 12 inch	12535	00618125161058
131182 (30883)	Disposable sterile cover set for C-arm with image intensifier max. 12 inch	12535	00618125175369
131183 (30885)	Disposable sterile cover for (Remote) Vision Center and (Remote) Solo Center	12535	00618125167036
131150 (31599)	Disposable sterile cover for Position Control Center	12535	00618125161065
131184 (30896)	Disposable sterile cover for C-Arm image intensifier housings max. 12 inch	12535	00618125167043
200-700-00 (33442)	Sterile DOC Cover 9" x 96"	12535	00618125188635
131924 (33196)	Disposable sterile cover set for C-arm with flat-panel detector max. 21 cm x 21 cm	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
5999417 (32863)	C-Arm Drape	12535	00618125152124
131925 (33195)	Disposable sterile cover set for C-arm with flat-panel detector max. 31 cm x 31 cm	12535	00618125182138
E7009AG (20862F)	Clear Dome Bag 27"	12535	00618125160488
E7009BD (20866F)	Clear Band Bag, 30" x 20"	12535	00618125160549





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Model Number (REF)	Product Name	GMDN	UDI-DI
ZGD20WA-LOOP	Zero-Gravity Equipment Cover	12535	00618125142965
5565	TIDIShield O-Arm Cover	12535	00618125140183
5574	Sterile-Z Patient Drape	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	00618125189328
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
00-902864-01 (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
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
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
5947412 (33330)	OEC 3D Disposable Drape Kit Detector and C-Arm Only	12535	00618125191086
5947413 (33331)	OEC 3D Disposable Drape Kit Full System with Accessories	12535	00618125191093
5791435 (33317)	OEC Disposables, 9-inch Image Intensifier OEC One	12535	00618125188857

# EU/UK/AU/CH Declaration of Conformity DC0016 Rev. 32

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

Product Name	Photo (if appropriate)
Sterile-Z Mayo Stand Cover (5582)	
Sterile-Z Back Table Cover (5575)	
C-Armor Drape (5523)	

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<p>Sterile-Z Patient Drape (5574)</p>	
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