EU/UK/AU/CH Declaration of Conformity
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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:	Sterile Equipment Covers, and Patient Drapes
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:	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.
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

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CH Legislation and Conformity Assessment Procedure:	Medical Device Regulation (EU) 2017/745, Annex IX Chapter I and III.	
Intended purpose:	• The medical barriers are intended to cover equipment to help maintain a sterile field. • The Sterile-Z patient drapes are intended for use with surgical patient to help maintain a sterile field.	
EMDN Code:	EMDN code for medical barriers, and surgical patient drapes: • T030102 – Cover Sheaths, Instruments and Equipment • T020199 Surgical Drapes Other (Sterile Z)	
Basic UDI-DI:	Basic UDI-DI for medical barriers: • 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	
MDR Certificate:	Number: MDR 766741	Issue Date: 2023-12-06
UKCA Certificate:	Number: UKCA 757280	Issue Date: 2021-12-07
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 2023-05-29
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 2023-05-29
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.	

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	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

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 (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 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 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 (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 Authorised Representative in Switzerland for the above indicated products.

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

Name of TIDI Representative; Javorka Spalevic	**Title, Function**	**Date**
Approval: Javorka Spalevic	**Approval:** Regulatory Product Manager	08/27/2024

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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
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 (10260)	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 Cover 40 inch x 84 inch/102 cm x 213 cm	12535	00618125152094
00-901501-01-OEC, E9100AG (20767)	OEC® 8800/9600/9800/9900 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

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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**
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 91 cm	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 Cover 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	12535	00618125152438
E7009CB (30352)	Sterile Drape	12535	00618125152445
E7009CC (30353)	Sterile Drape	12535	00618125152452
E7009CE (30728)	Kit for GE Innova 3100 X-Ray System	12535	00618125158270
E7009CF (30729)	Kit for GE Innova 4100 X-Ray System	12535	00618125152261
E7009HB (30802)	Sterile Flashpad 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 set 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
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

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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**
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 Drape	12535	00618125140213
5575	Sterile-Z® Back Table Cover	12535	00618125140220
5575-XL	Sterile-Z® Back Table Cover - Extra Large	12535	00618125141166
5582	Sterile-Z® Mayo Stand Cover	12535	00618125142422
CFI-705	X-Ray Cassette Cover 24" x 36"	12535	00618125140602
5774511 (33306)	OEC ® Disposables, 12 inch Image Intensifier 9800, 9900 & Elite™ 31cm CFM	12535	00618125187171
5845455 (33323)	OEC® Disposables	12535	00618125189274
5845456 (33324)	OEC® Disposables	12535	00618125189298
5857958 (33326)	OEC® Disposables	12535	00618125190041
5845457 (33325)	OEC® Disposables	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	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	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 Footswitch 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 with 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	12535	00618125188857

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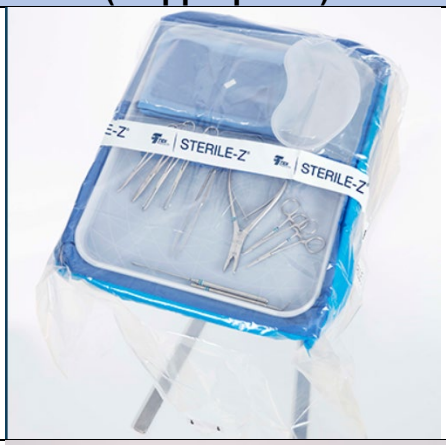
Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
12535	Medical equipment/instrument drape, single-use

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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Sterile-Z® Patient Drape (5574)