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, 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) Authorized Rep Contact Information:	MDSS-UK RP Ltd. 6 Wilmslow Road, Rusholme Manchester, M14 5TP UNITED KINGDOM Phone: +44 (0)7898 375115
Swiss (CH) Authorized Representative Contact Information:	NA
Product identification:	Zero-Gravity® Radiation Protection System
Technical File No.:	TF-0023 Zero-Gravity® Radiation Protection System Personal Protective Equipment (PPE)
Product Model Numbers:	See following page(s) for model numbers, and descriptions.
EU Legislation and Conformity Assessment Procedure:	1. EU Type Examination procedures under the requirements with Regulation (EU) 2016/425 relating to PPE Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II. 2. Conformity to Type based on Quality Assurance of the Production Process under the requirements with Regulation (EU) 2016/425 relating to PPE Annex VIII (Module D).
UK Legislation and Conformity Assessment Procedure:	1. UKCA Type Examination procedures under the requirements of the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2020 (SI 2020/676) relating to PPE Regulation 2016/425 Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II. 2. UKCA Conformity to Type based on Quality Assurance of the Production Process under the requirements of the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2020 (SI 2020/676) relating to PPE Regulation 2016/425 Annex VIII (Module D).

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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:	1. EU Type Examination procedures under the requirements with Regulation (EU) 2016/425 relating to PPE Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II. 2. Conformity to Type based on Quality Assurance of the Production Process under the requirements with Regulation (EU) 2016/425 relating to PPE Annex VIII (Module D).	
Intended purpose:	Zero-Gravity Radiation Protection System: A protective shield for use during medical procedures requiring fluoroscopy, intended to protect users from radiation exposure and orthopedic strain.	
EMDN Code:	NA	
Basic UDI-DI:	NA	
PPE Category in EU/CH:	Category III	
PPE Category in UK:	Category III	
Device Classification/ Rule in Australia (AU):	Class 1	Rule 2.1
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	N/A	
EC Certificate:	Number: CE 716486 (Annex V; Module B) CE 716567 (Annex VIII; Module D)	Issue Date: 15 Oct 2019 15 Oct 2019
UKCA Type -Certificate:	Number: UKCA 750690 (Annex V; Module B) UKCA 750691 (Annex VIII; Module D)	Issue Date: 18 Nov 2021 18 Nov 2021
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	

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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, United Kingdom MK5 8PP Approved Body Number 0086

For European Union (PPE 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 personal protective equipment complies with the applicable health and safety requirements to Annex II of the European Personal Protective Equipment Regulation 2016/425, and its relevant transposition into national laws of the member states into which the devices are placed and also self-declares compliance in part to the Machinery Directive 2006/42/EC as it applies to the overhead-body-shield-support functionality of the Zero-Gravity. We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

For United Kingdom (PPE 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 personal protective equipment complies with the requirements of the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2020 (SI 2020/676) relating to Regulation 2016/425 on personal protective equipment as brought into UK law and amended also self-declares compliance in part to the Machinery Directive (2006/42/EEC) implemented in the UK by the Supply of Machinery (Safety) (Amendment) Regulations 2011 as it applies to the overhead-body-shield-support functionality of the Zero-Gravity Systems. We explicitly designate MDSS-UK RP Ltd.to act as our sole Authorized Representative in the UK under PPE Regulation 2016/425 for the above indicated products.

For Australia (Non-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 technical documentation applies complies with the applicable provisions of the essential principles, and the classification rules before being supplied under clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods Administration Medical Device Regulation 2002.

For Switzerland (PPE 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 personal protective equipment complies with the applicable health and safety requirements of the European Personal Protective Equipment Regulation 2016/425, and its relevant transposition into national laws of the member states into which the devices are placed and also self-declares compliance in part to the Machinery Directive 2006/42/EC as it applies to the overhead-body-shield-support functionality of the Zero-Gravity. 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, in Neenah, WI 54956

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Name of TIDI Representative: Amanda Altan	Title, Function	Date
Approval: 	**Approval:** Senior Regulatory Affairs Manager	December 11, 2023

Product Model Number and Description to which this declaration applies.	
Model Numbers	**Description**
ZGCM-48	Zero-Gravity™ Radiation Protection System Monorail 48
ZGCM-66	Zero-Gravity™ Radiation Protection System Monorail 66
ZGHSA	Zero-Gravity™ Radiation Protection System Hinged Swing Arm
ZGCM-HSA	Zero-Gravity™ Radiation Protection System Monorail Hinged Swing Arm
ZGM-6-5H	Zero-Gravity™ Radiation Protection System Floor Unit
ZGCMRS	Zero-Gravity™ Monorail Leaded Acrylic Shield
ZG48	Zero-Gravity™ Radiation Protection System - Body Shield with Extension Rail
ZGHH-CMHSA	ZGM-6-5H Upgrade to ZGHH-CMHSA Zero-Gravity™ Radiation Protection System Upgrade from Floor to Hybrid Monorail Design
ZGHH-HSA	ZGM-6-5H Upgrade to ZGHH-HSA Zero-Gravity™ Radiation Protection System Upgrade from Floor to Hinged Swing Arm Design
ZGHH-66-CMHSA	ZGCM-48/ZGCM-66 Upgrade to ZGHH-66-CMHSA Zero-Gravity™ Radiation Protection System Upgrade Monorail 48/66 to Hybrid Monorail Design
ZGHH-CM48	ZGH-6-5H Upgrade to ZGHH-CM48 Zero-Gravity™ Radiation Protection System Upgrade from Floor to 48" Hybrid Monorail Design
ZGAV-XS	Zero-Gravity™ Radiation Protection System Extra Small Vest
ZGAV-S	Zero-Gravity™ Radiation Protection System Small Vest
ZGAV-M	Zero-Gravity™ Radiation Protection System Medium Vest
ZGAV-L	Zero-Gravity™ Radiation Protection System Large Vest
ZGAV-XL	Zero-Gravity™ Radiation Protection System Extra-Large Vest
ZGAV-2XL	Zero-Gravity™ Radiation Protection System Double Extra-Large Vest
ZGAV-3XL	Zero-Gravity™ Radiation Protection System Triple Extra-Large Vest

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Glossary of Global Medical Device Nomenclature (GMDN) Terms (for AU only)	
GMDN	**Term**
38373	Radiation shielding panel, portable/mobile

The products to which this declaration relates are developed and manufactured in conformity with the following standard(s).		
Number	**Description**	**Year/Revision**
DIN EN 61331-1	Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials (partial)	2016
DIN EN 61331-3	Protective devices against diagnostic medical X-radiation - Part 3: Protective clothing, eyewear and protective patient shields (partial)	2016
EN 166	Personal Eye-Protection - Specifications (partial)	2001
ANSI Z87.1	Eye & Face Protection Standards (partial)	2020
IEC 61331-1	Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials (partial)	2014
IEC 61331-2	Protective devices against diagnostic medical X-radiation – Part 2: Translucent protective plates (partial)	2014
IEC 61331-3	Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields (partial)	2014
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (partial)	2020
IEC 60601-1-3	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment (partial)	2021
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2020
ISO 14971	Medical devices – Application of risk management to medical devices	2019
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	2016
ISO 780	Packaging – Distribution packaging – Graphical symbols for handling and storage of packages	2015
ISPM 15	International Standard for Phytosanitary Measures 15	2018
ASTM D5445	Standard practice for pictorial markings for handling of goods	2021
EN 170	Personal Eye Protection - Ultraviolet Filters - Transmittance requirements and recommended use (partial)	2002
DIN EN 14238	Cranes - Manually controlled load manipulating devices (partial)	2010
EN ISO 12100	Safety Of Machinery - General principles for design - Risk assessment and risk reduction	2010
ISO 10993-1	Biological evaluation of medical devices. Evaluation and testing within a risk management process.	2018

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