Declaration of Conformity DC0006 Rev. 07

Manufacturer and Contact:	TIDI Products LLC 570 Enterprise Drive Neenah, WI 54956 USA	Management Representative: Amanda Altan Manager, Regulatory Affairs
Authorized Representative	Medical Device Safety Service GmbH Schiffgaben 41 30175 Hannover Germany	Telephone:49 511 6262 8630 Fax: 49 511 6262 8633
Conformity Assessment Procedure:	EU Type-examination (module B) set out in Annex V, followed by conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.	
Technical File No.:	TF-0023 Zero-Gravity® Radiation Protection System Personal Protective Equipment (PPE)	
Product Scope:	Zero-Gravity® Radiation Protection System	
Model Numbers:	See following page(s) for model numbers and descriptions.	
PPE Category:	Category III	
EC Type-Certificate:	Number: CE 716486 CE 716567	Issue Date: 15 Oct 2019 15 Oct 2019
Quality Management Certificate:	Number: FM 536366	Effective Date: 29 May 2020
Notified Body:	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 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, by the Manager of Regulatory Affairs; Amanda Altan, in Neenah, Wisconsin, USA.

Name of Authorized Person	**Title**	**Date**
Approval: Amanda Altan	**Regulatory Affairs Manager**	13 May 2021

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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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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	Radiation protection accessories for medical use of X-radiation – Part 1: Determination of shielding properties of unleaded or lead reduced protective clothing (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
EN 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 15223	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied	2016
ISO 780	Packaging – Distribution packaging – Graphical symbols for handling and storage of packages	2015
ISPM 15	International Standard for Phytosanitary Measures 15	2013
ASTM D5445	Standard practice for pictorial markings for handling of goods	2015
DIN EN 170	Personal Eye Protection - Ultraviolet Filters - Transmittance requirements and recommended use (partial)	2003
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
BS EN 1041	Information supplied by the manufacturer of medical devices	2008 +A1:2013
ISO 10993-1	Biological evaluation of medical devices. Evaluation and testing within a risk management process.	2018