TIDI PRODUCTS, LLC • 570 ENTERPRISE DRIVE • NEENAH, WI 54956
t. 920.751.4300 • f. 920.751.4370 • www.tidiproducts.com

Declaration of Conformity DC0032 Rev. 04

This is a declaration of conformity made under clause(s) 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002, Australia.

Manufacturer and Contact:	TIDI Products LLC 570 Enterprise Drive Neenah, WI 54956, USA	Management Representative: Amanda Altan Manager, Regulatory Affairs
Technical File No.:	TF-0023 Zero-Gravity® Radiation Protection System Personal Protective Equipment	
Product Scope:	Zero-Gravity® Radiation Protection System	
Model Numbers:	See following page(s) for model numbers, GMDNs, and descriptions.	
Device Classification:	Class I	
EC Certificate:	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.	
Conformity Route	Number: CE 716486 CE 716567	Issue Date: 15 October 2019 15 October 2019
MDSAP Certificate	Number: MDSAP 703786	Issue Date: 29 May 2020
Quality Management Certificate - ISO 13485	Number: FM 536366	Issue Date: 25 August 2017
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 Notified Body Number: 2797
Standards Applied:	See following pages for list of standards applied.	

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC. The devices referenced in this declaration are provided non-sterile.

The undersigned hereby declares, on behalf of TIDI Products, LLC, that the medical devices referenced in this declaration to which the system has been applied, complies with the applicable provisions of the essential principles, the classification rules, and the production quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

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Signed for on behalf of TIDI Products LLC, by the Manager of Regulatory Affairs; Amanda Altan, in Neenah, Wisconsin, USA.

Signature: Amanda Altan **Date:** 03 March 2022

Product Model Numbers, GMDN, and Description to which this declaration applies.

Model Numbers	GMDN	Description
ZGCM-48	38373	Zero-Gravity™ Radiation Protection System Monorail 48
ZGCM-66	38373	Zero-Gravity™ Radiation Protection System Monorail 66
ZGHSA	38373	Zero-Gravity™ Radiation Protection System Hinged Swing Arm
ZGCM-HSA	38373	Zero-Gravity™ Radiation Protection System Monorail Hinged Swing Arm
ZGM-6-5H	38373	Zero-Gravity™ Radiation Protection System Floor Unit
ZGCMRS	38373	Zero-Gravity™ Monorail Leaded Acrylic Shield
ZG48	38373	Zero-Gravity™ Radiation Protection System - Body Shield with Extension Rail
ZGHH-CMHSA	38373	ZGM-6-5H Upgrade to ZGHH-CMHSA Zero-Gravity™ Radiation Protection System Upgrade from Floor to Hybrid Monorail Design
ZGHH-HSA	38373	ZGM-6-5H Upgrade to ZGHH-HSA Zero-Gravity™ Radiation Protection System Upgrade from Floor to Hinged Swing Arm Design
ZGHH-66-CMHSA	38373	ZGCM-48/ZGCM-66 Upgrade to ZGHH-66-CMHSA Zero-Gravity™ Radiation Protection System Upgrade Monorail 48/66 to Hybrid Monorail Design
ZGHH-CM48	38373	ZGH-6-5H Upgrade to ZGHH-CM48 Zero-Gravity™ Radiation Protection System Upgrade from Floor to 48" Hybrid Monorail Design
ZGAV-XS	38373	Zero-Gravity™ Radiation Protection System Extra Small Vest
ZGAV-S	38373	Zero-Gravity™ Radiation Protection System Small Vest
ZGAV-M	38373	Zero-Gravity™ Radiation Protection System Medium Vest
ZGAV-L	38373	Zero-Gravity™ Radiation Protection System Large Vest
ZGAV-XL	38373	Zero-Gravity™ Radiation Protection System Extra-Large Vest
ZGAV-2XL	38373	Zero-Gravity™ Radiation Protection System Double Extra-Large Vest
ZGAV-3XL	38373	Zero-Gravity™ Radiation Protection System Triple Extra-Large Vest

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Glossary of Global Medical Device Nomenclature (GMDN) Terms	
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

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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 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