

EU Type Examination Certificate

This is to certify that:

TIDI Products LLC
570 Enterprise Drive
Neenah
Wisconsin
54956
USA

Holds Certificate Number:

CE 716486

In respect of:

**Model Zero Gravity Radiation Protection System
To Annex II of Regulation (EU) 2016/425**

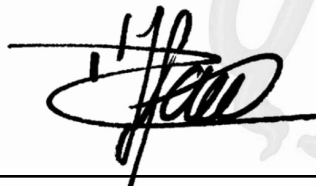
on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2019-10-15

Latest Issue: 2019-10-15



Drs. Dave Hagenaaers, Managing Director

Effective Date: 2019-10-15

Expiry Date: 2024-10-15

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EU Type Examination Certificate

No. CE 716486

Product Specification

Range: Zero Gravity Radiation Protection System

Product Description: The Zero-Gravity System consists of four key elements and interchangeable components which are essential to maintain the protective function, as well as accessories that may be used with the Zero-Gravity Radiation Protection System:

1. A Mechanical Support System to suspend the Body Shield, designed to balance the weight of the shield and to provide easy X-Y-Z displacement and rotation of that shield by the user. Four different designs of the mechanical support system are offered.
2. A Body Shield to provide radiation attenuation for the front and sides of the user. The upper part of the Body Shield is a transparent radiation-shield window, through which the user can observe the patient and procedure. This upper window part is sometimes termed the Face Shield; however, the term Body Shield refers to the entire radiation protector, from top to bottom.
3. A lightweight, Mesh Vest worn by the user, with a metal plate that engages with a magnet in the Body Shield so that the Body Shield follows the user's movements during a clinical procedure without the user having to hold, push or pull the shield using his or her hands.
4. A disposable Sterile Drape for the Body Shield. The drape is a medical device intended for use as a sterile cover to protect the patient (not to protect the Zero-Gravity user).

Models in Range:

Part Number	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

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Product Specification (continued)

Classification: Shoulder Shields LEV 1.00 mm
Body Shield Front LEV 1.00 mm
Body Shield Sides LEV 0.5 mm
Face shield LEV 0.5 mm
Eyeshield UV Scale Number 2-1.2/2C-1.2, Optical Class 1, Increased robustness S

Accessories:	Part Number	Description
	ZGCMRS	Zero-Gravity Monorail Leaded Acrylic Shield
	ZG48	Zero-Gravity Radiation Protection System - Body Shield with Extension Rail
	ZGHH-CMHSA	ZGCM-HSA Upgrade to ZGHH-CMHSA Zero-Gravity Radiation Protection System Upgrade from Floor to Hybrid Monorail Design
	ZGHH-HSA	ZGHSA 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	ZGM-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
	ZDG20WA-LOOP	Zero-Gravity Radiation Protection System Sterile Covers

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Product Specification (continued)

Technical Specification: Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425 using:
EN 61331-3:2014 Protective devices against diagnostic medical X-radiation, Part 3:
Protective clothing, eyewear and protective patient shields
EN 166:2001 Personal eye-protection — Specifications

Certificate Administration Details

Technical File Reference: 'Zero-Gravity Radiation Protection System, TECHNICAL FILE TF-0023'

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
October 2019	First issue under PPE Regulation (EU) 2016/425, product initially approved to Article 10 of the PPE Directive 89/686/EEC under TUV Sud issued certificate P5 15 04 85779 001, P5 14 09 85779 002 and P5 15 11 85779 003, with additional variants	2797:19:3061659

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Monitoring of manufactured PPE

The EC Quality of Production by Monitoring requirements, Module D, for the product are referenced in BSI issued Certificate Number CE 716567

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