

# UKCA Type Examination Certificate

This is to certify that:

TIDI Products, LLC  
570 Enterprise Drive  
Neenah  
Wisconsin  
54956  
USA

Holds Certificate Number:

UKCA 750690

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 of The Product Safety and Metrology etc (Amendment etc)(EU Exit) Regulations 2020 (SI 2020/676) relating to Personal Protective Equipment Regulation (PPE) 2016/425 Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II.

For and on behalf of BSI, an Approved  
Body for the above Regulation  
(Approved Body Number 0086):



Frank Lee, Product Certification Technical and Compliance Director

First Issued: 2021-11-18

Latest Issue: 2021-11-18

Effective Date: 2021-11-18

Expiry Date: 2026-11-18

Page: 1 of 4

...making excellence a habit.™

# UKCA Type Examination Certificate

No. UKCA 750690

## 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

First Issued: 2021-11-18

Latest Issue: 2021-11-18

Effective Date: 2021-11-18

Expiry Date: 2026-11-18

Page: 2 of 4

This certificate has been issued by and remains the property of BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, United Kingdom and should be returned immediately upon request.  
To check its validity telephone +44 (0) 345 080 9000. An electronic certificate can be authenticated [online](#).

BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.

# UKCA Type Examination Certificate

No. UKCA 750690

## 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 Lead 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

First Issued: 2021-11-18

Latest Issue: 2021-11-18

Effective Date: 2021-11-18

Expiry Date: 2026-11-18

Page: 3 of 4

This certificate has been issued by and remains the property of BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, United Kingdom and should be returned immediately upon request.  
To check its validity telephone +44 (0) 345 080 9000. An electronic certificate can be authenticated [online](#).

BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.

# UKCA Type Examination Certificate

No. UKCA 750690

## 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, Rev 3'

## Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
November 2021	Initial issue	0086:21:3445849

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

## Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate Number UKCA 750691

First Issued: 2021-11-18

Latest Issue: 2021-11-18

Effective Date: 2021-11-18

Expiry Date: 2026-11-18

Page: 4 of 4

This certificate has been issued by and remains the property of BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, United Kingdom and should be returned immediately upon request.  
To check its validity telephone +44 (0) 345 080 9000. An electronic certificate can be authenticated [online](#).

BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.