EU Declaration of Conformity

PRODUCT IDENTIFICATION
General Product Name
C Arm Imaging Table Appendix 1 has the listing of products with the device information.
CONFORMITY ASSESSMENT
Device Classification and Route to Compliance
Class I - Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

LEGAL MANUFACTURER		
Name of Company	**Address**	**Representative**
Medi-Plinth Equipment Ltd	7-11 Holywells Road, Ipswich, IP3 0DL	Tom Hart

EU AUTHORISED REPRESENTATIVE	
Name of Company	**Address**
EU Authorised Representative	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

EU CERTIFICATION	
Approved Body and ID #	**EU Certificate Number**
Self-declared device no Approved Body intervention required.	Number and expiry: N/A Date first applied: N/A

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

REPRESENTATIVE NAME: Tom Hart

TITLE: General Manager

SIGNATURE: 

DATE: 14.02.2024

PLACE OF ISSUE: Ipswich, UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix 1: Device Listing

Model Name	Model/Product Number	Intended Purpose	UDI-DI Number	GMDN/CND Code
C Arm Imaging Table	CTABLE001	Positioning table, with height adjustable arm/leg rest designed to be used with Imaging, Day Surgery, Vascular Studies and Pain Management Procedures	05060883540005	40680

Appendix 2: Harmonized Standards, Common Specifications, and other relevant EU legislation Listing

Identification Number	Title or Short Description	Version or Year
BS 8474	Furniture - Chairs with electrically operated support surfaces	2013
BS 8480	Medical Devices Chairs with electrically operated support surfaces	2006
BS EN ISO 13485	QMS for the Design & Manufacture of Medical Devices	2016
BS EN ISO 14971	Medical Devices – Application of Risk Management to Medical Devices	2019
BS EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements	2021
BS EN ISO 20417	Information supplied by the manufacturer of medical devices	2021
BS EN 60601-1	Medical Electrical Equipment. Part 1	2006
BS EN 60601-1-2	Medical Electrical Equipment. Part 1-2	2015
BS EN IEC 60601-2-46	Medical Electrical Equipment. Part 2-46	2019
BS EN 62366-1	Medical devices. Part 1: Application of usability engineering to medical devices	2015
2006/42/EC	Machinery Directive	2006

Revision History – starts at issue 1

Issue	Date	Description of Changes
01	14/02/2024	First edition