



EU Declaration of Conformity

PRODUCT IDENTIFICATION		
General Product Name		
Chairs, Couches, Plinths, Tables & Trolleys		
Appendix 1 has the listing of products with the device information.		
CONFORMITY ASSESSMENT		
Device Classification and Route to Compliance		
Device Classification	Route to Compliance	Standards Applied
Class I, Rule 1, Rule 13 (Electric)	Annex II and III (technical documentation) and Annex IV (DOC), and Annex V (applying the CE mark), of regulation MDR (EU) 2017/745	See below Appendix 2
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	

Medi-Plinth hereby declare under our exclusive responsibility the above-mentioned products meet the relevant provisions of the European Regulation (EU) 2017/745 for Medical Devices and those General Safety and Performance Requirements listed in Annex I; also, any applicable standards, any Common Specifications, or related European Union legislation.

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 (PRRC)

SIGNATURE:

DATE: 22nd April 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
Phlebotomy Chair Split Leg (Electric)	PH01E	Positioning chair used for phlebotomy and other medical procedures	05060883540340	10789
Phlebotomy Chair Single Leg (Electric)	PH02E		05060883540364	
Single Column Medical Chair (Electric)	MED04EC	Positioning chair used for ophthalmology and other medical procedures	05060883540722	15723
Drop End 3 Section Plinth (Electric)	DE03E	Positioning devices used for medical disciplines e.g. Gynaecology, Podiatry, Phlebotomy, Ophthalmology, Dialysis and Physiotherapy.	05060883540128	31362
Ensignia 2 Section Couch (Electric)	E2		05060883540029	
Ensignia 3 Section Plinth (Electric)	E3		05060883540036	
Echocardiography Plinth (Electric)	ECG03E		05060883540272	
Multi-Purpose Plinth (Electric)	MP03E		05060883540180	
Treatment/Plaster Split Leg (Electric)	PL01E		05060883540302	
Treatment/Plaster Single Leg (Electric)	PL02E		05060883540326	
2 Section Ocura Plinth (Electric)	OCURA+02E	Positioning devices used for physio procedure, and other medical procedures	05060883541033	32264
3 Section Ocura Plinth (Electric)	OCURA+03E		05060883541057	
Physio+ 2 Section Plinth (Electric)	PHYS+02E		05060883540821	
Physio+ 3 Section Plinth (Electric)	PHYS+03E	Positioning devices used for physio procedure, and other medical procedures	05060883540845	32264
Physio+ 4 Section Plinth (Electric)	PHYS+04E		05060883540869	
Physio+ 5 Section Plinth (Electric)	PHYS+05E		05060883540883	
Physio+ Bo Plnith (Electric)	PHYS+BOE		05060883540913	
Physio+ Bo Plnith Mat Table (Electric)	PHYS+MTE		05060883540920	
Single Column Tilting Medical Chair (Electric)	MED04ECT	Positioning chair used for medical disciplines e.g. Gynaecology, Podiatry, Phlebotomy, Ophthalmology, Dialysis and Physiotherapy.	05060883540739	36985
Medical Chair (Electric)	MED06E	Positioning chair used for medical disciplines e.g. Gynaecology, Podiatry, Phlebotomy, Ophthalmology, Dialysis and Physiotherapy.	05060883540388	38447
Medical Chair Tilting (Electric)	MEDT06E		05060883540395	



Echocardiography Plinth Tilting (Electric)	ECG03T	Positioning devices used for medical disciplines e.g. Gynaecology, Podiatry, Phlebotomy, Ophthalmology, Dialysis and Physiotherapy.	05060883540296	42486
40 Inch 2 Section Bo-Plinth (Electric)	BO01E	Positioning devices used for medical disciplines e.g. Gynaecology, Podiatry, Phlebotomy, Ophthalmology, Dialysis and Physiotherapy.	05060883540517	42577
GP Gynaecology Plinth with Foot Pads (Electric)	GY02EF	Positioning devices used for Gynaecology and other medical procedures	05060883540227	42855
GP Gynaecology Plinth with Stirrups (Electric)	GY02ES		05060883540203	
GP Gynaecology Plinth with Troughs (Electric)	GY02ET		05060883540210	
Ultra Gynaecology Plinth with Foot Pads (Electric)	GY04EF		05060883540258	
Ultra Gynaecology Plinth with Stirrups (Electric)	GY04ES		05060883540234	
Ultra Gynaecology Plinth with Troughs (Electric)	GY04ET		05060883540241	
Changing Table (Electric)	BA01E	Positioning devices used for medical examinations and treatments.	05060883540043	43694
2 Section Plinth (Electric)	BA02E		05060883540067	
3 Section Plinth (Electric)	BA03E		05060883540081	
Practice Plinth	PP02		05060883540951	
Tilt Table Single Section (Electric)	T01E	Positioning devices used for tilt table tests and other medical procedures	05060883540487	46763
Tilt Table Split Leg (Electric)	T02E		05060883540494	
Tilt Table 2 Section (Electric)	T03E		05060883540500	
Day Care Couch (Electric)	DC03E	Positioning devices used for medical disciplines e.g. Oncology, Podiatry, Phlebotomy, Ophthalmology, Dialysis and Physiotherapy.	05060883540678	47117
Outpatients 2 Section Plinth (Electric)	OP02E		05060883540401	
Outpatients 3 Section Plinth (Electric)	OP03E		05060883540425	
Podiatry Chair Non-Tilting (Electric)	BAC06E	Positioning devices used for Podiatry and other medical procedures	05060883540142	47150
Podiatry Chair Electric Tilting (Electric)	BTC06E		05060883540159	



Bariatric 2 section 100cm (Electric)	BARI02100	Positioning devices suitable for bariatric patients used for medical disciplines e.g. Gynaecology, Podiatry, Phlebotomy, Ophthalmology, Dialysis and Physiotherapy.	05060883540562	58419
Bariatric 2 section 75cm (Electric)	BARI0275		05060883540555	
Bariatric 3 section 100cm (Electric)	BARI03100		05060883540586	
Bariatric 3 section 100cm Drop End (Electric)	BARI03100DE		05060883540609	
Bariatric 3 section 75cm (Electric)	BARI0375		05060883540579	
Bariatric 3 section 75cm Drop End (Electric)	BARI0375DE		05060883540593	
Ultrasound Plinth (Electric)	US03TE	Positioning devices used for ultrasounds and other medical procedures	05060883540265	62694

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	22/03/2022	First edition
02	14/02/2024	Discontinued products removed
03	22/04/2024	Revised to amend references to include references to EU 2017/745 and reviewed to remove hydraulic plinths to separate DoC