



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

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
Phlebotomy Chair Split Leg (Electric)	PH01E	Positioning chair used for phlebotomy and other medical procedures	05060883540340	10789
Phlebotomy Chair Split Leg (Hydraulic)	PH01H		05060883540357	
Phlebotomy Chair Single Leg (Electric)	PH02E		05060883540364	
Phlebotomy Chair Single Leg (Hydraulic)	PH02H		05060883540371	
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
Drop End 3 Section Plinth (Hydraulic)	DE03H		05060883540135	
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	
Multi-Purpose Plinth (Hydraulic)	MP03H		05060883540197	
Treatment/Plaster Split Leg (Electric)	PL01E		05060883540302	
Treatment/Plaster Split Leg (Hydraulic)	PL01H		05060883540319	
Treatment/Plaster Single Leg (Electric)	PL02E		05060883540326	
Treatment/Plaster Single Leg (Hydraulic)	PL02H		05060883540333	
2 Section Ocura Plinth (Electric)	OCURA+02E		Positioning devices used for physio procedure, and other medical procedures	
2 Section Ocura Plinth Hydraulic	OCURA+02H	05060883541040		
3 Section Ocura Plinth (Electric)	OCURA+03E	05060883541057		
3 Section Ocura Plinth Hydraulic	OCURA+03H	05060883541064		
Physio+ 2 Section Plinth (Electric)	PHYS+02E	05060883540821		
Physio+ 2 Section Plinth (Hydraulic)	PHYS+02H	05060883540838		



Physio+ 3 Section Plinth (Electric)	PHYS+03E	Positioning devices used for physio procedure, and other medical procedures	05060883540845	32264
Physio+ 3 Section Plinth (Hydraulic)	PHYS+03H		05060883540852	
Physio+ 4 Section Plinth (Electric)	PHYS+04E		05060883540869	
Physio+ 4 Section Plinth (Hydraulic)	PHYS+04H		05060883540876	
Physio+ 5 Section Plinth (Electric)	PHYS+05E		05060883540883	
Physio+ 5 Section Plinth (Hydraulic)	PHYS+05H		05060883540890	
Physio+ Bo Plinth (Electric)	PHYS+BOE		05060883540913	
Physio+ Bo Plinth 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 (Hydraulic)	MED06H		5060883541262	
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
Changing Table (Hydraulic)	BA01H		05060883540050	
2 Section Plinth (Electric)	BA02E		05060883540067	
2 Section Plinth (Hydraulic)	BA02H		05060883540074	
3 Section Plinth (Electric)	BA03E		05060883540081	
3 Section Plinth (Hydraulic)	BA03H		05060883540098	
Practice Plinth	PP02		050608835400951	
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 2 Section Plinth (Hydraulic)	OP02H		05060883540418	
Outpatients 3 Section Plinth (Electric)	OP03E		05060883540425	
Outpatients 3 Section Plinth (Hydraulic)	OP03H		05060883540432	
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