EU Declaration of Conformity

PRODUCT IDENTIFICATION		
General Product Name		
Hydraulic 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 (Hydraulic)	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: 16th August 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
Multi-Purpose Plinth (Hydraulic)	MP03H	Manually-operated positioning chair used during a diagnostic examination, medical treatment, and/or surgical procedure across specialties.	05060883540197	36985
Medical Chair (Hydraulic)	MED06H		5060883541262	
Phlebotomy Chair Split Leg (Hydraulic)	PH01H		05060883540357	
Phlebotomy Chair Single Leg (Hydraulic)	PH02H		05060883540371	
Treatment/Plaster Split Leg (Hydraulic)	PL01H		05060883540319	
Treatment/Plaster Single Leg (Hydraulic)	PL02H		05060883540333	
Practice Plinth	PP02	A non-mobile table designed for routine/minor medical examinations and/or treatment of the patient.	05060883540951	38458
2 Section Plinth (Hydraulic)	BA02H	Manually-operated positioning devices used for routine/minor medical examinations and/or treatment	05060883540074	42486
3 Section Plinth (Hydraulic)	BA03H		05060883540098	
40 Inch 2 Section Bo-Plinth (Hydraulic)	BO01H		05060883540524	
Drop End 3 Section Plinth (Hydraulic)	DE03H		05060883540135	
2 Section Ocura Plinth Hydraulic	OCURA+02H		05060883541040	
3 Section Ocura Plinth Hydraulic	OCURA+03H		05060883541064	
Outpatients 2 Section Plinth (Hydraulic)	OP02H		05060883540418	
Outpatients 3 Section Plinth (Hydraulic)	OP03H		05060883540432	
Physio+ 2 Section Plinth (Hydraulic)	PHYS+02H		05060883540838	
Physio+ 3 Section Plinth (Hydraulic)	PHYS+03H		05060883540852	

Physio+ 4 Section Plinth (Hydraulic)	PHYS+04H		05060883540876	
Physio+ 5 Section Plinth (Hydraulic)	PHYS+05H		05060883540890	
Changing Table (Hydraulic)	BA01H	Manually-operated positioning devices used for changing patient with a disability	05060883540050	43544

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
04	15/08/2024	Correction to GMDN numbers, Treatment/Plaster chairs and Bo Plinth added