

EU Declaration of Conformity

For MR Patient Transportation Wheelchairs

Basic UDI-DI: 506500603700GMDN40699LP

Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 concerning Medical Devices.

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed. This declaration is issued under the sole responsibility of the manufacturer.

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| General Product Name: | MR Patient Transportation Wheelchairs |
| Legal Manufacturer: (Name on Label) | Wardray Premise Limited, Unit 2 Springvale Works, Elland Road, Brighouse, West Yorkshire, HD6 2RN United Kingdom |
| Manufacturers SRN: | GB-MF-000021675 |
| Variants: | As per Appendix II (This document) – Product Listing/Schedule |
| Intended Purpose: | Patient Transport to and from MRI Department |
| MDR Classification: | Class I |
| Notified Body: | Not Applicable for Class I |
| EC Certificate: | Not Applicable as we self-certify Class I devices. |
| EU Authorised Representative: | Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta. |
| EU Authorised Representative SRN: | MT-AR-000000234 |
| Medical Device Regulation Assessment Route: | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. |

Name Justine Colquhoun Position Director

Signed  Date 15/07/2022 Place KT7 OSP (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 I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

| Standard/Document Name | Description |
|------------------------|--|
| 2017/745 | Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 concerning Medical Devices |
| BS EN 12183 | Specification for Manually Propelled Wheelchairs |
| EN 1041:2008 | Information supplied by the manufacturer of medical devices |
| EN ISO 13485:2016 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2012 | Medical Devices – Application of Risk Management to Medical Devices |

Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Device Name | EMDN Code |
|-----------------------|--------------------------------------|-----------|
| MR4500 | MR Folding Portering Chair | 40699 |
| MR4501 | MR Non Folding Portering Chair | 40699 |
| MR4588 | MR Folding Bariatric Portering Chair | 40699 |
| FGPC-200 | Ferrous Free Portering Chair | 40699 |

Version History

| Version | Compiled by | Date | Description |
|---------|---------------|------------|---|
| 1.0 | J C Colquhoun | 30/10/2019 | First issue |
| 2.0 | J C Colquhoun | 27/05/2021 | Amended to include basic UDI-DI |
| 3.0 | J C Colquhoun | 02/07/2021 | Removal of reference to Annex IX under Medical Device Regulation Assessment Route |
| 4.0 | J C Colquhoun | 09/12/2021 | Addition of FGPC-200 Portering Chair |
| 5.0 | J C Colquhoun | 15/07/2022 | Addition of Manufacturers SRN number |