

### EU Declaration of Conformity

For MR Patient Transportation Trolleys

**Basic UDI-DI: 506500603700GMDN46148LP**

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.

|  |   |
|--|---|
| <b>General Product Name:</b>                       | MR Patient Transportation Trolleys  |
| <b>Legal Manufacturer:<br/>(Name on Label)</b>     | Wardray Premise Limited, Unit 2 Springvale Works, Elland Road, Brighouse, West Yorkshire, HD6 2RN United Kingdom  |
| <b>Manufacturers SRN:</b>                          | GB-MF-000021675   |
| <b>Variants:</b>                                   | As per Appendix II (This document) – Product Listing/Schedule   |
| <b>Intended Purpose:</b>                           | Patient Transport to and from MRI Department  |
| <b>MDR Classification:</b>                         | Class I Classification rule 1 from Annex VIII of the MDR directive specifies that all non-invasive devices are classified as class 1 unless one of the other rules listed is applicable.  |
| <b>Notified Body:</b>                              | Not Applicable for Class I  |
| <b>EC Certificate:</b>                             | Not Applicable as we self-certify Class I devices.  |
| <b>EU Authorised Representative:</b>               | Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.  |
| <b>EU Authorised Representative SRN</b>            | MT-AR-000000234   |
| <b>Medical Device Regulation Assessment Route:</b> | In conformity with Annex IX of the Medical Device Regulation. 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      **Place** Head Office, Sutton, Surrey  
**Signed** Justine Colquhoun      **Date** 25/03/2024

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 5402:1976                 | Specification for patient Trolleys   |
| BS EN ISO 20417:2021         | Information supplied by the manufacturer of medical devices  |
| EN ISO 13485:2016            | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes                            |
| EN ISO 14971:2019 + A11:2021 | Medical Devices – Application of Risk Management to Medical Devices  |
| BS EN ISO 15223-1:2021       | Medical Devices – Symbols to be used with medical device labels  |
| PDC EN ISO/TR 24971:2020     | Guidance on the application of ISO 14971   |

## Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Device Name                             | EMDN Code |
|-----------------------|---|-----------|
| MR5501                | MR Adjustable Height Trolley            | 46148     |
| MR5501/P              | MR Paediatric Adjustable Height Trolley | 46148     |
| MR1501                | MR Fixed Height Trolley                 | 46148     |
| MR1501/P              | MR Paediatric Fixed Height Trolley      | 46148     |
| MR1510                | MR Economy Fixed Height Trolley         | 46148     |
| MR1505                | MR Cube Trolley Fixed Height            | 46148     |
| MR5505                | MR Cube Trolley Adjustable Height       | 46148     |
| FGTT200               | Ferrous Free Fixed Height Trolley       | 46148     |
| MR5502                | MR Adjustable Height Patient Trolley    | 46148     |

## 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 FGTT-200 Trolley  |
| 5.0     | J C Colquhoun | 15/07/2022 | Addition of Manufacturers SRN number  |
| 6.0     | J C Colquhoun | 26/03/2024 | Addition of MR5502 Trolley  |