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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.

General Product Name:	MR Patient Transportation Trolleys
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, 2nd 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 Justine Colquhoun **Date** 15/07/2022 **Place** KT7 0SP (UK)

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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
BS5402:1976	Specification for patient Trolleys
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
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

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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