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EU Declaration of Conformity

For X-Ray Patient Transportation Trolleys

Basic UDI-DI: 5065006037GMDN46148XRAYBL

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:	X-Ray 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 X-Ray Department and for facilitating emergency x-rays.
MDR Classification:	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.
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 Directive Assessment Route:	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
BS5402:1976	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 62353 : 2014	Medical Electrical Equipment – Recurrent test & test after repair. (XRT4000 only)
BS EN ISO 15223-1:2021	Medical Devices – Symbols to be used with Medical Device labels
PDCEN ISO/TR 24971:2020	Guidance on the application of ISO 14971
BS EN ISO 60601-1:2006 + A2 2021	Medical Electrical Equipment – General requirement for basic safety and essential performance (XRT4000 only)

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
XRT4000	X-Ray Adjustable Height Trolley	46148
XRT1000	X-Ray Fixed Height Trolley	46148

Version History

Version	Compiled by	Date	Description
1.0	J C Colquhoun	30/10/2019	First issue
2.0	J C Colquhoun	30/06/2021	Amended to include basic UDI-DI
3.0	J C Colquhoun	15/07/2022	Addition of Manufacturers SRN number
4.0	J C Colquhoun	25/03/2024	Update of British Standards