

## 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.

<b>General Product Name:</b>	X-Ray Patient Transportation Trolleys
<b>Legal Manufacturer: (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 X-Ray Department and for facilitating emergency x-rays
<b>MDR Classification:</b>	Class I
<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>	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

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
IEC62353 : 2014	Collateral Standards : Electromagnetic compatibility (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