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EU Declaration of Conformity

For MRI Mobile I.V Stand
Basic UDI-DI:506500603700GMDN36069LF

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:	MRI Mobile I.V Stand
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:	None
Intended Purpose:	To enable infusion in MRI Room
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 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

Signed Justine Colquhoun **Date** 15/07/2021

Registered in England No. 347881

Registered Office: Hampton Court Estate, Summer Road, Thames Ditton, Surrey 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
BS3619:1976	Specification for Mobile I.V Pole
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
EN ISO 15223:2016	Medical Devices – Symbols to be used in Medical Devices
EN ISO10993-1	Biological Evaluation of Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
MR2500	MRI Mobile I.V Stand	61952

Version History

Version	Compiled by	Date	Description
1.0	J C Colquhoun	20/12/2019	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