

Declaration of Conformity

for the Comfort Value Recline & Toileting Slings

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Comfort Value Recline & Toileting Sling
Legal Manufacturer: (Name on Label)	Care & Independence, Unit 3 Telford Business Centre, Telford Road Bicester, OXON OX26 4LD, UNITED KINGDOM
Manufacturers SRN:	GB-MF-000029352
Basic UDI-DI:	506044694CVDLSLINGH6
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	General-purpose patient lifting system sling/harness
MDR Classification:	Class 1 by Rule 1, Annex IX
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd 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 Jim Ash **Position** Technical & Operations Director

Signed  **Date** 24/10/2022 **Place** United Kingdom

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 (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Name	EMDN #
CVR-XXS / 5060446946756	Comfort Value RECLINE SIZE XXS	V08050399
CVR-XS / 5060446946763	Comfort Value RECLINE SIZE XS	V08050399
CVR-S / 5060446946770	Comfort Value RECLINE SIZE S	V08050399
CVR-M / 5060446946787	Comfort Value RECLINE SIZE M	V08050399
CVR-L / 5060446946794	Comfort Value RECLINE SIZE L	V08050399
CVR-XL / 5060446946800	Comfort Value RECLINE SIZE XL	V08050399
CVR-XXL / 5060446946817	Comfort Value RECLINE SIZE XXL	V08050399
CVR-HB-XXS / 5060446946824	Comfort Value RECLINE HIGH BACK SIZE XXS	V08050399
CVR-HB-XS / 5060446946831	Comfort Value RECLINE HIGH BACK SIZE XS	V08050399
CVR-HB-S / 5060446946848	Comfort Value RECLINE HIGH BACK SIZE S	V08050399
CVR-HB-M / 5060446946855	Comfort Value RECLINE HIGH BACK SIZE M	V08050399
CVR-HB-L / 5060446946862	Comfort Value RECLINE HIGH BACK SIZE L	V08050399
CVR-HB-XL / 5060446946879	Comfort Value RECLINE HIGH BACK SIZE XL	V08050399
CVR-HB-XXL / 5060446946886	Comfort Value RECLINE HIGH BACK SIZE XXL	V08050399
CVT-XS / 5060446946893	Comfort Value TOILETING SIZE XS	V08050399
CVT-S / 5060446946909	Comfort Value TOILETING SIZE S	V08050399
CVT-M / 5060446946916	Comfort Value TOILETING SIZE M	V08050399
CVT-L / 5060446946923	Comfort Value TOILETING SIZE L	V08050399
CVT-XL / 5060446946930	Comfort Value TOILETING SIZE XL	V08050399
CVPT-XS / 5060446946947	Comfort Value POLY TOILETING SIZE XS	V08050399
CVPT-S / 5060446946954	Comfort Value POLY TOILETING SIZE S	V08050399
CVPT-M / 5060446946961	Comfort Value POLY TOILETING SIZE M	V08050399
CVPT-L / 5060446946978	Comfort Value POLY TOILETING SIZE L	V08050399
CVPT-XL / 5060446946985	Comfort Value POLY TOILETING SIZE XL	V08050399

Version History

Version	Compiled by	Date	Description
1.0	Jim Ash	30/06/2022	Upgrade to structure.
1.1	Jim Ash	24/10/2022	Addition of SRN