

Declaration of Conformity

for the Comfort Value Deluxe, Universal and Hybrid 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 Deluxe, Universal and Hybrid Slings
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:	506044694CVGENSLING8G
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 #
CVU-XXS / 5060446945636	Comfort Value UNIVERSAL SIZE XXS	V08050399
CVU-XS / 5060446945643	Comfort Value UNIVERSAL SIZE XS	V08050399
CVU-S / 5060446945650	Comfort Value UNIVERSAL SIZE S	V08050399
CVU-M / 5060446945667	Comfort Value UNIVERSAL SIZE M	V08050399
CVU-L / 5060446945674	Comfort Value UNIVERSAL SIZE L	V08050399
CVU-XL / 5060446945681	Comfort Value UNIVERSAL SIZE XL	V08050399
CVU-XXL / 5060446945698	Comfort Value UNIVERSAL SIZE XXL	V08050399
CVUP-XXS / 5060446945704	Comfort Value UNIVERSAL POLY SIZE XXS	V08050399
CVUP-XS / 5060446945711	Comfort Value UNIVERSAL POLY SIZE XS	V08050399
CVUP-S / 5060446945728	Comfort Value UNIVERSAL POLY SIZE S	V08050399
CVUP-M / 5060446945735	Comfort Value UNIVERSAL POLY SIZE M	V08050399
CVUP-L / 5060446945742	Comfort Value UNIVERSAL POLY SIZE L	V08050399
CVUP-XL / 5060446945759	Comfort Value UNIVERSAL POLY SIZE XL	V08050399
CVUP-XXL / 5060446945766	Comfort Value UNIVERSAL POLY SIZE XXL	V08050399
CVU-HB-XXS / 5060446945773	Comfort Value UNIVERSAL HIGH BACK SIZE XXS	V08050399
CVU-HB-XS / 5060446945780	Comfort Value UNIVERSAL HIGH BACK SIZE XS	V08050399
CVU-HB-S / 5060446945797	Comfort Value UNIVERSAL HIGH BACK SIZE S	V08050399
CVU-HB-M / 5060446945803	Comfort Value UNIVERSAL HIGH BACK SIZE M	V08050399
CVU-HB-L / 5060446945810	Comfort Value UNIVERSAL HIGH BACK SIZE L	V08050399
CVU-HB-XL / 5060446945827	Comfort Value UNIVERSAL HIGH BACK SIZE XL	V08050399
CVU-HB-XXL / 5060446945834	Comfort Value UNIVERSAL HIGH BACK SIZE XXL	V08050399
CVUP-HB-XXS / 5060446945841	Comfort Value UNIVERSAL POLY HIGH BACK SIZE XXS	V08050399
CVUP-HB-XS / 5060446945858	Comfort Value UNIVERSAL POLY HIGH BACK SIZE XS	V08050399

Catalogue Number / UDI-DI	Device Name	EMDN #
CVUP-HB-S / 5060446945865	Comfort Value UNIVERSAL POLY HIGH BACK SIZE S	V08050399
CVUP-HB-M / 5060446945872	Comfort Value UNIVERSAL POLY HIGH BACK SIZE M	V08050399
CVUP-HB-L / 5060446945889	Comfort Value UNIVERSAL POLY HIGH BACK SIZE L	V08050399
CVUP-HB-XL / 5060446945896	Comfort Value UNIVERSAL POLY HIGH BACK SIZE XL	V08050399
CVUP-HB-XXL / 5060446945902	Comfort Value UNIVERSAL POLY HIGH BACK SIZE XXL	V08050399
CVUPS-XXS / 5060446945919	Comfort Value UNIVERSAL POLY 6 STRAP SIZE XXS	V08050399
CVUPS-XS / 5060446945926	Comfort Value UNIVERSAL POLY 6 STRAP SIZE XS	V08050399
CVUPS-S / 5060446945933	Comfort Value UNIVERSAL POLY 6 STRAP SIZE S	V08050399
CVUPS-M / 5060446945940	Comfort Value UNIVERSAL POLY 6 STRAP SIZE M	V08050399
CVUPS-L / 5060446945957	Comfort Value UNIVERSAL POLY 6 STRAP SIZE L	V08050399
CVUPS-XL / 5060446945964	Comfort Value UNIVERSAL POLY 6 STRAP SIZE XL	V08050399
CVUPS-XXL / 5060446945971	Comfort Value UNIVERSAL POLY 6 STRAP SIZE XXL	V08050399
CVUPS-HB-XXS / 5060446945988	Comfort Value UNIVERSAL POLY 6 STRAP HIGH BACK SIZE XXS	V08050399
CVUPS-HB-XS / 5060446945995	Comfort Value UNIVERSAL POLY 6 STRAP HIGH BACK SIZE XS	V08050399
CVUPS-HB-S / 5060446946008	Comfort Value UNIVERSAL POLY 6 STRAP HIGH BACK SIZE S	V08050399
CVUPS-HB-M / 5060446946015	Comfort Value UNIVERSAL POLY 6 STRAP HIGH BACK SIZE M	V08050399
CVUPS-HB-L / 5060446946022	Comfort Value UNIVERSAL POLY 6 STRAP HIGH BACK SIZE L	V08050399
CVUPS-HB-XL / 5060446946039	Comfort Value UNIVERSAL POLY 6 STRAP HIGH BACK SIZE XL	V08050399
CVUPS-HB-XXL / 5060446946046	Comfort Value UNIVERSAL POLY 6 STRAP HIGH BACK SIZE XXL	V08050399
CVH-1 / 5060446946053	Comfort Value HYBRID SIZE 1	V08050399
CVH-2 / 5060446946060	Comfort Value HYBRID SIZE 2	V08050399
CVH-3 / 5060446946077	Comfort Value HYBRID SIZE 3	V08050399
CVH-4 / 5060446946084	Comfort Value HYBRID SIZE 4	V08050399
CVH-5 / 5060446946091	Comfort Value HYBRID SIZE 5	V08050399
CVH-6 / 5060446946107	Comfort Value HYBRID SIZE 6	V08050399
CVH-7 / 5060446946114	Comfort Value HYBRID SIZE 7	V08050399
CVH-8 / 5060446946121	Comfort Value HYBRID SIZE 8	V08050399

Catalogue Number / UDI-DI	Device Name	EMDN #
CVH-9 / 5060446946138	Comfort Value HYBRID SIZE 9	V08050399
CVH-10 / 5060446946145	Comfort Value HYBRID SIZE 10	V08050399
CVH-11 / 5060446946152	Comfort Value HYBRID SIZE 11	V08050399
CVH-12 / 5060446946169	Comfort Value HYBRID SIZE 12	V08050399
CVHP-1 / 5060446946176	Comfort Value HYBRID PLUS SIZE 1	V08050399
CVHP-2 / 5060446946183	Comfort Value HYBRID PLUS SIZE 2	V08050399
CVHP-3 / 5060446946190	Comfort Value HYBRID PLUS SIZE 3	V08050399
CVHP-4 / 5060446946206	Comfort Value HYBRID PLUS SIZE 4	V08050399
CVHP-5 / 5060446946213	Comfort Value HYBRID PLUS SIZE 5	V08050399
CVHP-6 / 5060446946220	Comfort Value HYBRID PLUS SIZE 6	V08050399
CVHP-7 / 5060446946237	Comfort Value HYBRID PLUS SIZE 7	V08050399
CVHP-8 / 5060446946244	Comfort Value HYBRID PLUS SIZE 8	V08050399
CVHP-9 / 5060446946251	Comfort Value HYBRID PLUS SIZE 9	V08050399
CVHP-10 / 5060446946268	Comfort Value HYBRID PLUS SIZE 10	V08050399
CVHP-11 / 5060446946275	Comfort Value HYBRID PLUS SIZE 11	V08050399
CVHP-12 / 5060446946282	Comfort Value HYBRID PLUS SIZE 12	V08050399
CVHF-4 / 5060446946299	Comfort Value HYBRID FOXY SIZE 4	V08050399
CVHF-5 / 5060446946305	Comfort Value HYBRID FOXY SIZE 5	V08050399
CVHF-6 / 5060446946312	Comfort Value HYBRID FOXY SIZE 6	V08050399
CVHF-7 / 5060446946329	Comfort Value HYBRID FOXY SIZE 7	V08050399
CVHF-8 / 5060446946336	Comfort Value HYBRID FOXY SIZE 8	V08050399
CVHF-9 / 5060446946343	Comfort Value HYBRID FOXY SIZE 9	V08050399
CVHF-10 / 5060446946350	Comfort Value HYBRID FOXY SIZE 10	V08050399
CVHF-11 / 5060446946367	Comfort Value HYBRID FOXY SIZE 11	V08050399
CVHF-12 / 5060446946374	Comfort Value HYBRID FOXY SIZE 12	V08050399
CVHFP-4 / 5060446946381	Comfort Value HYBRID FOXY PLUS SIZE 4	V08050399
CVHFP-5 / 5060446946398	Comfort Value HYBRID FOXY PLUS SIZE 5	V08050399
CVHFP-6 / 5060446946404	Comfort Value HYBRID FOXY PLUS SIZE 6	V08050399
CVHFP-7 / 5060446946411	Comfort Value HYBRID FOXY PLUS SIZE 7	V08050399
CVHFP-8 / 5060446946428	Comfort Value HYBRID FOXY PLUS SIZE 8	V08050399
CVHFP-9 / 5060446946435	Comfort Value HYBRID FOXY PLUS SIZE 9	V08050399
CVHFP-10 / 5060446946442	Comfort Value HYBRID FOXY PLUS SIZE 10	V08050399
CVHFP-11 / 5060446946459	Comfort Value HYBRID FOXY PLUS SIZE 11	V08050399
CVHFP-12 / 5060446946466	Comfort Value HYBRID FOXY PLUS SIZE 12	V08050399
CVHF-PB-4 / 5060446946473	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 4	V08050399
CVHF-PB-5 / 5060446946480	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 5	V08050399
CVHF-PB-6 / 5060446946497	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 6	V08050399

Catalogue Number / UDI-DI	Device Name	EMDN #
CVHFPB-7 / 5060446946503	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 7	V08050399
CVHFPB-8 / 5060446946510	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 8	V08050399
CVHFPB-9 / 5060446946527	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 9	V08050399
CVHFPB-10 / 5060446946534	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 10	V08050399
CVHFPB-11 / 5060446946541	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 11	V08050399
CVHFPB-12 / 5060446946558	Comfort Value HYBRID FOXY PLUS 3 LOOPS SIZE 12	V08050399
CVD-XXS / 5060446946619	Comfort Value DELUXE SIZE XXS	V08050399
CVD-XS / 5060446946626	Comfort Value DELUXE SIZE XS	V08050399
CVD-S / 5060446946633	Comfort Value DELUXE SIZE S	V08050399
CVD-M / 5060446946640	Comfort Value DELUXE SIZE M	V08050399
CVD-L / 5060446946657	Comfort Value DELUXE SIZE L	V08050399
CVD-XL / 5060446946664	Comfort Value DELUXE SIZE XL	V08050399
CVD-XXL / 5060446946671	Comfort Value DELUXE SIZE XXL	V08050399
CVD-HB-XXS / 5060446946688	Comfort Value DELUXE HIGH BACK SIZE XXS	V08050399
CVD-HB-XS / 5060446946695	Comfort Value DELUXE HIGH BACK SIZE XS	V08050399
CVD-HB-S / 5060446946701	Comfort Value DELUXE HIGH BACK SIZE S	V08050399
CVD-HB-M / 5060446946718	Comfort Value DELUXE HIGH BACK SIZE M	V08050399
CVD-HB-L / 5060446946725	Comfort Value DELUXE HIGH BACK SIZE L	V08050399
CVD-HB-XL / 5060446946732	Comfort Value DELUXE HIGH BACK SIZE XL	V08050399
CVD-HB-XXL / 5060446946749	Comfort Value DELUXE HIGH BACK SIZE XXL	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