

# EU DECLARATION OF CONFORMITY



We,  
Drive DeVilbiss Healthcare Ltd,  
Sidhil Business Park,  
Holmfield,  
Halifax,  
West Yorkshire,  
HX2 9TN,  
UK  
(SRN: GB-MF-000012818)

Hereby declare under our sole responsibility that the devices specified are in conformity with:

Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

**EU authorised representative:** Advena Ltd., Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta  
(SRN: MT-AR-000000234)

**General product name:** Casa Elite bed range

**Product variants:** See Appendix 1

**GMDN code:** 30032

**BASIC UDI-DI:** 50551544ABD006XS

**Intended purpose:** The intended use of the bed is to support the weight of the patient, whilst sleeping or resting and to assist the end user to gain and/or maintain a suitable position.

**Risk class:** Medical device class I as defined by rule 13 of Annex VIII of EU 2017/745.

**Conformity assessment procedure:** 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 regulation EU 2017/745

The medical devices to which this declaration relates comply with the following standards:

EN 60601-1:2006+A12:2014	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-2-52:2010+A1:2015	Medical Electrical Equipment – Part 2-52: Particular requirements for basic safety and essential performance of medical beds.
EN 60601-1-6:2010+A1:2015	Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance. Collateral Standard: Usability.
EN 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN ISO 14971:2012	Medical devices- Application of risk management to medical devices.
EN ISO 15223-1:2016	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer.

Signed for and on behalf of Drive DeVilbiss Healthcare Ltd.

Name: Mr Alastair Fry  
Title: Head of international regulatory affairs and compliance  
Date of Issue: 23<sup>rd</sup> May 2022  
Place of Issue: Drive DeVilbiss Healthcare Ltd, Halifax, HX2 9TN, UK

## Appendix 1

### Product variants:

- |                       |                                     |
|-----------------------|-------------------------------------|
| • CASA/C/LOW/(COLOUR) | Casa Elite Low – Covered bed ends   |
| • CASA/H/LOW/(COLOUR) | Casa Elite Low – Uncovered bed ends |
| • CASA/C/STD/(COLOUR) | Casa Elite – Covered bed ends       |
| • CASA/H/STD/(COLOUR) | Casa Elite – Uncovered bed ends     |

The Casa Elite beds are available in 3 colour variants. '(COLOUR)' to be replaced with:

- |        |           |
|--------|-----------|
| ○ BECH | Beech     |
| ○ LOAK | Light Oak |
| ○ WALN | Walnut    |