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: IQ bed range

Product variants:		**UDI-DI:**
• IQ/AQ	Innov8 IQ bed	05055154400508
• IQ/AQ/150	Innov8 IQ bed with 150 castors	05055154404230
• IQ/AQ/SR	Innov8 IQ bed with standard cantilever side rails	05055154408276
• IQ/AQ/HSR	Innov8 IQ bed with high cantilever side rails	05055154408269
• IQ/AQ/SSR	Innov8 IQ bed with split side rails	05055154408283

GMDN: 30032
EMDN: V08060101

BASIC UDI-DI: 50551544ABD001XG

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 ISO 14971:2012	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 – Part 1: General requirements.
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: 10th July 2024
Place of Issue: Drive DeVilbiss Healthcare Ltd, Halifax, HX2 9TN, UK