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: Inspiration 2 Cot

Product variants:		**UDI-DI:**
• 9004/MPBA	Standard cot	05055154408214
• 9005/MPBA	Standard cot + CPR function	05055154408238

GMDN: 37010

EMDN: V0806010701

BASIC UDI-DI: 50551544CBD001YA

Intended purpose: The intended purpose of the cot is to support the weight of the patient and allow the patient to maintain a suitable position in respect to the clinical need.

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+A1:2013	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
EN 50637: 2017	Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of medical beds for children.
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 medical device labels, labelling and information to be supplied.
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer.
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

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: 3rd October 2023

Place of Issue: Drive DeVilbiss Healthcare Ltd, Halifax, HX2 9TN, UK