UK 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 device specified is in conformity with:

The Medical Devices Regulations 2002 (SI 2002, No 618) as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020, No. 1478)

General product name:	Apollo II pump
Product code:	APOLLO/2/PUMP
GMDN:	36688
BASIC UDI-DI:	50557857DPC002F8
UDI-DI:	05055785718362
Intended purpose:	The air pump is intended to inflate/deflate the specified mattress or cushion, to provide pressure redistribution to patients who are at risk of, or who have developed, a pressure related tissue injury.
Risk class:	Medical device class IIa as defined by rule 9 of Annex IX of EU directive 93/42/EEC – as identified by UK regulation SI 2002 No 618, Part II, regulation 7.
UK approved body:	SGS United Kingdom Ltd. Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN
UK approved body number:	0120
Conformity assessment procedure:	Fulfilling the obligations imposed by Annex II, excluding section 4, of EU directive 93/42/EEC – as defined by UK regulation SI 2002 No 618, Part II, regulation 13 (2).
Certificate issued:	GB23/00000186
Standards compliance:	See Appendix 1

Signed for and on behalf of Drive DeVilbiss Healthcare Ltd.

Name: Alastair Fry
Title: Head of international regulatory affairs and compliance
Date of Issue: 18th May 2023
Place of Issue: Drive DeVilbiss Healthcare Ltd, Halifax, HX2 9TN, UK

Appendix 1

The medical device to which this declaration relates is in compliance with the following designated standards:

EN 60601-1:2006+A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
EN 60601-1-6:2010	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 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management Process

The medical device to which this declaration relates is in compliance with the following additional standards:

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 62304:2006+A1:2015	Medical device software - Software life-cycle processes
EN ISO 20342-1:2022	Assistive products for tissue integrity when lying down – Part 1: General requirements
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