# 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)

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|---|---|
| **General product name:** | Apollo Junior dynamic mattress (surface only) |
| **Product variants:** | JUNIOR/MAT |
| **GMDN:** | 63641 |
| **BASIC UDI-DI:** | 50557857DPC003FA |
| **UDI-DI:** | 05055785718461 |
| **Intended purpose:** | The mattress is intended to support the weight of the patient whilst sleeping /resting and to assist the user with pressure distribution as part of an overall plan of care. |
| **Risk class:** | Medical device class I as defined by rule 1 of Annex IX of EU directive 93/42/EEC – as defined by UK regulation SI 2002 No 618, Part II, regulation 7. |
| **Conformity assessment procedure:** | Fulfilling the obligations imposed by Annex VII of EU directive 93/42/EEC – as defined by UK regulation SI 2002 No 618, Part II, regulation 13 (1). |
| **Standards compliance:** | See Appendix 1 |

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: 4th September 2022
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:

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|---|---|
| EN 60601-1:2006+A1:2013 (partial*) | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. |
| EN 60601-1-11:2010 (partial*) | 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 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 ISO 15223-1:2016 | Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. |
| 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 |
| EN ISO 10993-5: 2009 | Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity |

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

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|---|---|
| EN 60601-1:2006+A12:2014 (partial*) | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. |
| EN 60601-1-11:2015 (partial*) | 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 20342-1:2019 | 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 |
| EN ISO 10993-10:2010 | Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization |
| BS 7175:1989 | Methods of test for the ignitability of bedcovers and pillows by smouldering and flaming ignition sources |

* For those clauses that are relevant to the mattress surface only, when considered in combination with APOLLO/2/PUMP.