


Declaration of Conformity

for the NoDec Range of Pressure Re-distribution Mattresses

ROBER LIMITED, Speed Plastics Limited, declares that the medical devices described hereafter are in conformity with the requirements and provisions of Council Directive 93/42/EEC for **CLASS 1** medical devices.

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

| | |
|--|--|
| General Product Name: | Pressure Relief Mattress |
| Legal Manufacturer: (Name on Label) | <u>Rober Limited</u> Wheatbridge Road Chesterfield Derbyshire S40 2AB |
| Manufacturers SRN: | Not Yet Available |
| BASIC UDI-DI: | 50612176PRESSCAREMATT6D |
| Variants: | As per Appendix II (This document) – Product Listing/Schedule |
| Intended Purpose: | Pressure Relieving Mattress System for Prevention of Pressure Ulcers |
| MDD Classification: | Class 1 (low risk) device that pose almost no risk to patient safety Rule 13 |
| Notified Body: | Not Applicable |
| EC Certificate: | Self Certification Class 1 |
| EU Authorised Representative: | Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta. |
| EU Authorised Representative SRN: | MT-AR-000000234 |
| Medical Device Regulation Assessment Route: | Issuing of the Declaration of Conformity in accordance with MDD 93/42/EEC after drawing up the technical documentation for Class 1 Rule 13 |

Name Michael Hutson **Position** Managing Director
Signed  **Date** 15 May 2024 **Place** Chesterfield UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

| Standard/CS/Document Name | Description |
|--|--|
| 93/42/EEC | Medical Device Directive 93/42/EEC |
| EN ISO 13485:2016+A11:2021 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2012 / ISO 14971:2019 | 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 - General requirements |
| EN ISO 20417:2021 | Medical devices. Information to be supplied by the manufacturer |
| EN 60601-1 EN 60601-1-2 | Medical Electrical Equipment-General Requirements |
| EN 55011 | Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. |
| EN 61000-4-2 EN 61000-4-3 EN 61000-4-5 EN 61000-4-8 | Electromagnetic compatibility (EMC) |
| EN 12182 | Assistive products for persons with disability |
| EN 597-1 | Assessment of the ignitability of mattress and upholstered bed bases |
| BS 6807 Clause 9 | Methods of test for assessment of ignitability of mattresses |
| BS 7175:1989 ignition source 0, 1 & 5 | Methods of test for the ignitability of bedcovers and pillows |
| BS EN ISO 12952:2010 | Textiles Assessment of the ignitability of bedding items |

Appendix II – Product Listing/Schedule

| Catalogue Number UDI-DI GTIN | Device Name | GMDN/EMDN Code |
|---------------------------------|----------------------------|-----------------|
| 5060121762312 | NoDec Airstream | 63241 / V080701 |
| 5060121761803 | NoDec Airstream2 | 63241 / V080701 |
| 5060121762541 | NoDec Airstream THP | 63241 / V080701 |
| 5060121761773 | NoDec Airstream3 | 63241 / V080701 |
| 5060121761711 | NoDec Airstream3 Kingsize | 63241 / V080701 |
| 5060121761742 | NoDec Airstream BARI | 63241 / V080701 |
| 5060121762534 | NoDec Airstream BARI COMBO | 63241 / V080701 |
| 5060121762299 | NoDec Wizard | 63241 / V080701 |
| 5060121761544 | NoDec Wizard Low Profile | 63241 / V080701 |
| | | |

Version History

| Version | Compiled by | Date | Description |
|---------|-------------|-------------|----------------------------|
| 1.0 | Mike Hutson | 26 May 2021 | Original |
| 1.1 | Mike Hutson | 28 Nov 2022 | Amended to Class 1 Rule 13 |
| 1.2 | Mike Hutson | 15 May 2024 | Amendment to Basic B-UDI |