VAN ROON

Van Roon Medische Techniek B.V.
Leiden, the Netherlands

# EU declaration of conformity

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| **Manufacturer** | Van Roon Medische Techniek B.V., Leiden, the Netherlands |
| **Product** | VR-7 intensive-care bed, all variants and accessories listed in the instructions for use |
| **Model** | VR-7, catalogue numbers VR7-0001 to VR7-0006 |
| **Intended purpose** | Powered hospital bed for adult patients (see the instructions for use) |
| **Classification** | Class I medical device, rule 1 |
| **Legislation** | Regulation (EU) 2017/745 on medical devices; Directive 2011/65/EU on the restriction of hazardous substances |
| **Standards applied** | EN 60601-1:2006+A2:2021; EN 60601-1-2:2015+A1:2021; EN 60601-2-52:2010+A1:2015; EN ISO 14971:2019; EN 62366-1:2015; EN 60601-1-6:2010 |

We declare under our sole responsibility that the product named above meets the provisions of the legislation listed that apply to it. As a Class I device it has been assessed by the manufacturer; no conformity assessment body has been involved.

The technical documentation is held by the manufacturer in Leiden.

Leiden, 28 April 2025

Maarten Kloosterboer
Managing Director, Van Roon Medische Techniek B.V.

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Van Roon Medische Techniek B.V.
Leiden, the Netherlands

# UK declaration of conformity

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|---|---|
| **Manufacturer** | Van Roon Medische Techniek B.V., Leiden, the Netherlands |
| **UK Responsible Person** | Van Roon Medical UK Ltd, Unit 3, Tarnfield Way, Morley, Leeds LS27 0YT, United Kingdom |
| **Product** | VR-7 intensive-care bed, all variants and accessories listed in the instructions for use |
| **Model** | VR-7, catalogue numbers VR7-0001 to VR7-0006 |
| **Intended purpose** | Powered hospital bed for adult patients (see the instructions for use) |
| **Classification** | Class I medical device, rule 1 |
| **Legislation** | The Medical Devices Regulations 2002 (SI 2002 No 618), as amended; the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 |
| **Standards applied** | EN 60601-1:2006+A2:2021; EN 60601-1-2:2015+A1:2021; EN 60601-2-52:2010+A1:2015; EN ISO 14971:2019; EN 62366-1:2015; EN 60601-1-6:2010 |

We declare under our sole responsibility that the product named above meets the provisions of the legislation listed that apply to it. As a Class I device it has been assessed by the manufacturer; no conformity assessment body has been involved.

The technical documentation is held by the manufacturer in Leiden and is available to the UK Responsible Person.

Leiden, 28 April 2025

Maarten Kloosterboer
Managing Director, Van Roon Medische Techniek B.V.