VAN ROON

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

EU declaration of conformity

Manufacturer	Van Roon Medische Techniek B.V., Leiden, the Netherlands
Product	VR-7 XW bariatric intensive-care bed, all variants and accessories listed in the instructions for use
Model	VR-7 XW, catalogue numbers VRX-0001 and VRX-0002
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.

VAN ROON

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

UK declaration of conformity

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 XW bariatric intensive-care bed, all variants and accessories listed in the instructions for use
Model	VR-7 XW, catalogue numbers VRX-0001 and VRX-0002
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.