

NRS Healthcare , Blaris Industrial Estate 4C Altona Road, Lisburn, Northern Ireland BT27 5QB

(SRN: XI-AR-000031974)

NRS Healthcare, Sherwood House, Cartwright Way, Forest Business Park, Bardon Hill, Coalville,

Leicestershire LE67 1UB, UK. (SRN: GB-MF-000034983)

Declare, upon our sole responsibility, that our product;

Item Number: M48192

Basic UDI-DI: 5038948481921

Item name: 2 in 1 Bedrail MK 2



Being a Class I Medical Device (GMDN code: 34868)

Complies with the appropriate requirements of EC Council Directives:-

Regulation 2017/745 - Medical Devices Directive

Directive 93/42/EEC as amended by Directive 2007/47/EEC – Medical Devices Regulation (& amendments)

Regulation 1907/2006 (& amendments) - Registration, Evaluation, Restriction & Authorisation of Chemicals

The product complies with the appropriate requirements of the listed harmonised or national standards:

BS EN ISO 21856:2022 Assistive products – General requirements and test methods.

BS EN 60601-2-52:2010 Medical Electrical Equipment. Particular requirements for basic safety and essential performance of electrical beds.

Intended Use:

To provide stable support to aid adult users (taller than 1.46 m) transfer in and out of bed, moving from a lying to a sitting position as well as assist user repositioning. For use with solid base divan beds and framed beds with fixed slats

Declaration of Conformity Date: June 2024



Signed Jan Snuth

Ian Smith

Quality Manager

Date: July 2024

LYCE

Date: June 2024