Declaration of Conformity

Patient Fall Recovery Chair (DOC-TF105)

Direct Healthcare Group Ltd, hereby declare that the products identified below confirm to the requirements of the Medical Device Regulation 2017/475 and Directives 2014/30/EU (Electromagnetic Compatibility), 2014/35/EU (Low voltage), 2012/19/EU (Waste Electrical and Electronic Equipment (WEEE) Directive) and 2011/65/EU (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment).

This Declaration of Conformity is issued under the sole responsibility of Direct Healthcare Group Ltd.

Declaration Ref:	DOC-TF105
General Product Name:	Patient Fall Recovery Chair
Date of Declaration of Conformity:	27 February 2026
Manufacturer:	Direct Healthcare Group Ltd Withey Court, Western Industrial Estate, Caerphilly, CF83 1BF, United Kingdom
Manufacturer SRN:	UK-MF-000037574
Product Code:	As per Appendix I – Product Listing/Schedule
Intended Use:	The Raizer is a mobile lifting chair which helps a lying person up to an almost standing position in a few minutes. The Raizer can be operated by only a single person
EMDN:	V080503 – Patient Transfer Lifts
Basic-UDI-DI:	506057201PFRC6R
Measuring function:	No
Sterile:	No
Standards referenced or applied:	As per Appendix II – Applicable Standards
Conformity assessment Procedure:	Regulation (EU) 2017/745 on medical devices (MDR) Annex II and III
Regulation Classification:	Class I Rule 1
Notified Body:	N/A
EC Certificate Ref:	N/A
EU Authorised Representative:	Direct Healthcare Group Sverige AB (DHG AB) Torshamnsgatan 35, SE-164 40 Kista, Sweden SE-AR-000014155
Australian Sponsor	Direct Healthcare Group PTY LTd, 67 Howe Street, Osborne Park, Western Australia 6017

Declaration of Conformity

Patient Fall Recovery Chair (DOC-TF105)

Moving Health Forward

Sign for and on behalf of Direct Healthcare Group by:

R.W.Macdonald

R W Macdonald — Caerphilly, United Kingdom

Group Regulatory Affairs Director — 27th Feb 2026

Version History

Revision	Compiled by	Date	Description
3.0	R.W. Macdonald	27/02/2026	Updated format and corrected Declaration Reference
2.0	R.W. Macdonald	21/01/2025	Updated format
1.0	J Campbell	14/11/2022	Initial release for MDR

Appendix I – Product Listing/Schedule

Catalogue Ref	Device Name
105040	Raizer M
107760	Raizer M + Headrest
107763	Raizer M + Headrest and Cover
105029	Raizer II
107761	Raizer II + Headrest

Appendix II – Applicable Standards

The current Declaration of Conformity is also in conformity with the following European Standards and Common Specifications (CS):

Reference	Version/Year	Title
BS EN ISO 13485	2016+A11:2021	Medical devices. Quality management systems. Requirements for regulatory purposes
BS EN ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices
BS EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1. Evaluation and testing within a risk management process
BS EN ISO 15223-1	2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
BS EN ISO 20417	2021	Medical devices. Information to be supplied by the manufacturer
BS EN 62304*	2006+A1:2015	Medical device software. Software life-cycle processes
BS EN 60601-1*	2006+A2:2021	Medical electrical equipment - General requirements for basic safety and essential performance
BS EN 60601-1-2*	2015+A1:2021	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
BS EN 60601-1-6*	2010+A2:2021	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral standard: Usability

Reference	Version/Year	Title
BS EN 60601-1-8*	2007+A2:2021	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
BS EN 60601-1-11*	2015+A1:2021	Medical electrical equipment - 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
BS EN 60601-1-12*	2015+A1:2020	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
BS EN 62366-1	2015+A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices
BS EN 10535	2021	Assistive products - Hoists for the transfer of persons - Requirements and test methods (ISO 10535:2021, Corrected version 2023-08)
BS EN 21856	2022	Assistive products - General requirements and test methods (ISO 21856:2022)

Note: * - applicable to the powered version only

Appendix III – Additional Information

No Additional information is required.