Declaration of Conformity
Raizer II Patient Lifting Chair - Powered

Moving Health Forward

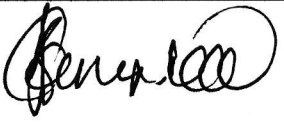
Direct Healthcare Group Ltd., Withey Court, Western Industrial Estate, Caerphilly, United Kingdom, CF83 1BF hereby declare that the products identified below conform to the requirements of the Medical Device Regulations 2017/745.

Product Details	
Product Name	See schedule
Legal Manufacturer	Direct Healthcare Group Limited, Withey Court, Western Industrial Estate, Caerphilly, United Kingdom, CF83 1BF
Intended Use	A battery powered system intended to be used to lift a person lying on the floor to a seated position
Device classification	Class I under rule 1 and 13 of Annex VIII
Route to classification	Self-certification following compliance with the requirements of Annex II and Annex III of MDR 2017/745.

The following standards have been used to fulfil the requirements of the Medical Device Regulations:

Standard/Document Name	Description
BS EN 60601-1:2006+A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
BS EN 60601-1-2:2015	Electromagnetic disturbances – Requirements and tests
BS EN 60601-1-11:2015	Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment
BS EN 60601-1-6:2010+A1:2015	Usability
BS EN 60601-1-8:2007+A11:2017	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
BS EN 60601-1-12:2015+A1:2020	Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
BS EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes
BS EN 62366-1:2015 (Annex C 2015)	Medical Devices – Part 1: Application of usability engineering to medical devices
BS EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
BS EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical device
BS EN ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
BS EN 10535:2006	Hoists for the transfer of disabled persons – Requirements and test methods
BS EN ISO 13485: 2016	Medical devices — Quality management system
BS EN ISO 14971:2019	Medical devices – Application of risk management to medical devices

Representative/Sponsor	Address
EU Authorised Representative	Direct Healthcare Group Sverige AB, Torshamnsgatan 35, SE-164 40 Kista, Sweden
Australian sponsor	Direct Healthcare Group PTY Ltd., 67 Howe Street, Osborne Park, Western Australia 6017

Signature: 

Date: 14 November 2022

Jo Campbell, QARA Director, Direct Healthcare Group Limited, Caerphilly, United Kingdom

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Schedule – Product Listing

Description	Product Code	Basic UDI
Raizer II	105029	05060572010369

Direct Healthcare Group
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