Declaration of Conformity

Patient Turning Sheet System (DOC-104)

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-104
General Product Name:	Vendlet Patient Turning System
Date of Declaration of Conformity:	January 2025
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:	Intended for moving clients to a lateral, prone, or supine position, from one side of the bed to the other, or, to reposition them further up in bed. The system may also be used in connection with mobilisation in and out of bed and when transferring clients from one bed to another.
EMDN:	V0805 – Patient Transport System
Basic-UDI-DI:	506057201PTSSA2
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 (Annex VIII)
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

Sign for and on behalf of Direct Healthcare Group by:

R W Macdonald — Direct Healthcare Group Ltd.
Group Regulatory Affairs Director — 18/03/2025

Version History

Revision	Compiled by	Date	Description
3.0	R.W. Macdonald	18/03/2025	Updated part numbers
2.0	R.W. Macdonald	21/01/2025	Updated format
1.0	J Campbell	16/06/2022	Initial release for MDR

Appendix I – Product Listing/Schedule

Catalogue Ref	Device Name
6300000	Vendlet Standard
6100000	Vendlet V5S
6100150	Vendlet V5S Bari
6100050	Vendlet V5S Speed Adjust
6300003	VENDLET Standard, with Velcro

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
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

Reference	Version/Year	Title
BS EN 60601-2-52	2010+A1:2015	Medical electrical equipment - Particular requirements for basic safety and essential performance of medical beds
BS EN 21856	2022	Assistive products - General requirements and test methods (ISO 21856:2022)
BS 7177	2008 + A1:2011	Specification for resistance to ignition of mattresses, mattress pads, divans and bed bases

Appendix III – Additional Information

No Additional information is required.