Declaration of Conformity
VENDLET Patient Turning Systems

DHG
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	Patient transfer aids for turning and repositioning patients in bed.
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
IEC 60601-1:2005+A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Electromagnetic disturbances – Requirements and tests
IEC 60601-1-11:2015	Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment
IEC 62366:2015	Medical Devices – Part 1: Application of usability engineering to medical devices
EN 60601-2-52:2009 + Cor.:2010 + A1:2015 (applicable clauses)	Medical electrical equipment - Part 2-52: Special requirements for basic safety and essential performance of medical beds
EN ISO 15223-1:2020	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical device
BS EN ISO 10993-5:2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
BS EN ISO 10993-10:2013	Biological evaluation of medical devices. Tests for irritation and skin sensitization
BS 7177:2008+A1:2011	Specification for resistance to ignition of mattresses, mattress pads, divans and bed bases
BS EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
EN ISO 13485: 2016	Medical devices — Quality management system
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: 16 June 2022

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

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Schedule – Product Listing

Description	Product Code	Basic UDI
VENDLET V5S	6100000	05060572010161
VENDLET V5S Speed Adjust	6100050	05060572010178
VENDLET V5S Bari	6100150	05060572010185
VENDLET Standard	6300000	05060572010154

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