

Declaration of Conformity for Floor Lifts

Direct Healthcare Group - United Care confirm the requirements specified in the Medical Device Regulation 2017/745 have been fulfilled. The undersigned has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out operations in accordance with these instructions.

General Product Name	See Appendix II
Legal Manufacturer	United Care Products BV Bremenweg 5 9723 TC, Groningen The Netherlands
Applicable standards/ Common specifications	As per Appendix I
Intended Use	Floor lift systems are indoor movable and portable units which together with approved accessories assisting in lifting and/or transferring users in a seated or supine position, over short distances between two points.
MDR Directive Classification	Class I
Registration Agency	NOTIS/ Farmatec
Medical Device Assessment Route:	Annex II of the Medical Device Regulation (EU) 2017/745

Name Bob Janssen

Position Quality & Regulatory Consultant

Signature *Bob M Janssen*
Bob M Janssen (Dec 16, 2022 14:11 GMT+1)

Date & Place 2022-12-22 / Groningen

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Appendix I – Applicable Standards

Following standards are used to fulfil the Medical Device Regulations and Requirements:

Standard	Description
IEC 60601-1-6: 2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 12182:2012	Assistive products for persons with disability – General requirements and test methods
EN ISO 10535:2006	Hoists for the transfer of disabled persons – Requirements and test methods
ISO 10993-1:2018	Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (Reference 9)
IEC 60601-1:2005/A1: 2012/ A2:2020 EN 60601-1:2006 and A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 + A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11:2015 + A1:2020	Medical electrical equipment - Part 1-11: 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.
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical device
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

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Appendix II – Product Listing

Description	Article no
Tilly home	11000500
Tilly basic + two-point sling bar	11000482
Tilly basic + electrical four-point sling bar	11000480
Tilly basic + four-point sling bar	11000481
Wendy 160 + two-point sling bar	11000510
Wendy 160 + four-point electric sling bar	11000530
Wendy 160 + four-point sling bar	11000550
Wendy 230 + two-point sling bar	11000570
Wendy 230 + four-point electric sling bar	11000590
Wendy 230 + four-point sling bar	11000610
Wendy 230 heightened + two-point sling bar	11000630
Wendy 230 heightened + four-point electric sling bar	11000650
Wendy 230 heightened + four-point sling bar	11000670
Tracey	22000020
WendyDrive + two-point spreader bar	11000720
WendyDrive + four-point tilting electrical spreader bar	11000730

Revision log

Version	Date	Amendment
1.0	23/05/2021	First issue MDR compliance
2.0	2022-12-22	Added WendyDrive