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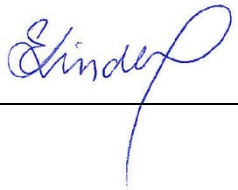
Declaration of Conformity for Floor Lifts

Direct Healthcare Group Sverige AB confirm the requirements specified in the Medical Device Regulation 2017/745 have been fulfilled. The EU declaration of conformity is issued under the sole responsibility of DHG Sverige AB. 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	Direct Healthcare Group Sverige AB Torshamnsgatan 35 164 40 Kista Sweden
Applicable standards/ Common specifications	As per Appendix I
Intended Use	Sliding sheets and Bed Covers are intended to be used for manual transfers, turning and positioning of users who have difficulties turning in bed. The Sliding Sheets enable transfer, turning or positioning to be performed without friction and without causing damage of the skin of the user.
MDR Classification	Class I, Rule I
Single Registration no (SRN):	SE-MF-000014152
Registration Agency	Swedish Medical Products Agency
Assessment Route	Annex II of the European Medical Device Regulation (EU) 2017/745

Name	Elisabet Lindberg	**Position**	Head of Quality and Environmental EU
Signature		**Date and Place**	Kista 2023-07-13

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Appendix I – Applicable Standards

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

Standard	Description
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
EN ISO 20417:2021	Information supplied by the manufacturer of medical device
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 10993-1:2018	Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (Reference 9)
EN ISO 13485: 2016	Medical devices — Quality management systems
IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012 IEC 60601-1-6: 2010+ AMD1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-2:2014	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	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
ISO 10535:2021	Hoists for the transfer of disabled persons — Requirements and test method

Appendix II – Product Listing

Description	Article No	Basic UDI
Eva450EE	60100002	7331769004934
Eva600EE	60100003	7331769004941
Eva 450EEL	60100006	7331769019679
Eva600EEL	60100010	7331769019686
Eva450EELJ	60100006J	7331769032760
Eva450EMLJ	60100013J	7331769020309
Vega505EE	60600003	7331769020422
Eva 600Drive	60900003	7331769034986
Carina350 EE	60600009	7331769022587
Carina 350 EM	60600011	7331769014209
Carina350 EML	60600012	7331769030919
Mikuni Mighty Light III	60600013	7331769031459
Carina350EEL	60600014	7331769033538

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Revision log

Version	Date	Amendment
3.0	2023-07-13	Review of continued relevance; removed GMDN information; updated standards not related to testing of the products to current versions.
2.0	2021-05-25	First page typo in the table, Directive changed to Regulation.
1.0	2021-05-19	First issue MDR compliance