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Direct Healthcare Group
Advancing Movement & Health

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 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	Floor lift systems are indoor movable and portable units which together with approved accessories assist in lifting and/or transferring users in a seated or supine position, over short distances between two points.
MDR Classification	Class I
Registration Agency	Swedish Medical Products Agency
Medical Device Regulation Assessment Route:	Annex II of the Medical Device Regulation (EU) 2017/745

Name Roshana Eriksson **Position** Head of QARA EU

Signature  **Date and Place** 25/05/2021 Kista

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Appendix I – Applicable Standards

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

Standard/Document Name	Description
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
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
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 10535:2006	Hoists for the transfer of disabled persons — Requirements and test method

Appendix II – Product Listing

Description	Article no	Basic UDI	GMDN
Eva450EE	60100002	07331769004934	12330
Eva600EE	60100003	07331769004941	12330
Eva450EEL	60100006	07331769019679	12330
Eva600EEL	60100010	07331769019686	12330
Vega505EE	60600003	07331769020422	12330
Carina350EE	60600009	07331769022587	12330
Carina350EM	60600011	07331769014209	12330
Carina350EML	60600012	07331769030919	12330
Mikuni Mighty Light III	60600013	07331769031459	12330
Carina350EEL	60600014	07331769033538	12330
Eva450EELJ	60100006J	07331769032760	12330
Eva450EMLJ	60100013J	07331769020309	12330

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Revision log

Version	Date	Amendment
1.0	19/05/2021	First issue MDR compliance
2.0	25/05/2021	First page typo in the table, Directive changed to Regulation.