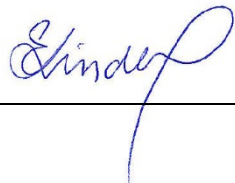


## Declaration of Conformity for Floor Lifts

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 manufacturer's instructions, and has carried out operations in accordance with these instructions.

<b>General Product Name</b>	See Appendix II
<b>Legal Manufacturer</b>	Direct Healthcare Group Sverige AB Torshamnsgatan 35 164 40 Kista Sweden
<b>Applicable standards/ Common specifications</b>	As per Appendix I
<b>Intended Use</b>	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.
<b>MDR Classification</b>	Class I, Rule I and XIII
<b>Single Registration no (SRN):</b>	SE-MF-000014152
<b>Registration Agency</b>	Swedish Medical Products Agency
<b>Assessment Route</b>	Annex II of the European Medical Device Regulation (EU) 2017/745

<b>Name</b>	Elisabet Lindberg	<b>Position</b>	Head of Quality and Environmental EU; PRRC
<b>Signature</b>		<b>Date and Place</b>	Kista 2025-12-05

## Appendix I – Applicable Standards

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

Standard	Description
EN ISO 13485: 2016	Medical devices — Quality management systems
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 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
IEC 60601-1:2005/ AMD1:2012; AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6: 2010+ AMD1:2013 IEC 60601-1-6:2010/ AMD1:2013; AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1- 2:2014/AMD1:2020	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	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
Eva 450EE	60100002	7331769004934
Eva600EE	60100003	7331769004941
Eva 450EE, with low legs	60100006	7331769019679
Eva450EE, with low legs, for Japan	60100006J	7331769032760
Eva 600EE with low legs	60100010	7331769019686
Eva 450EM, with low legs for Japan	60100013J	7331769020309
Eva 450EM, with low legs for Singapore	60100013S	7331769479039