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Direct Healthcare Group
Advancing Movement & Health

Declaration of Conformity for Movers

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	Movers are indoor movable and portable units intended to support a person with reduced muscular strength, via self-raising mechanism, from a sitting to standing positioning or during sitting transfers over short distances. Mover Aqua is intended to be used in Home Healthcare environment and Professional Healthcare facility environment.
MDR Classification	Class I, Rule I
Eudamed Registration no/ SRN:	SE-MF-000014152
Registration Agency	Swedish Medical Product Agency
Assessment Route	Annex II of the European Medical Device Regulation (EU) 2017/745

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

Signature **Date and Place** 08/10/2021 Kista

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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 -Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices -Application of risk management to medical devices
EN ISO 10993-1:2020	Biological Evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
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	Medical devices – Information to be supplied by the manufacturer
EN 12182:2012	Assistive products for persons with disability – General requirements and test methods

Appendix II – Product Listing

Description	Article no	Basic UDI	GMDN
Mover Aqua	53-301	07350013533013	37953
Mover PLUS, 150 kg brukarvikt	53-302	07350013533020	37953