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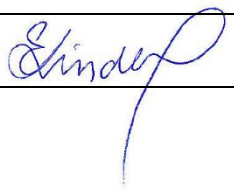
Declaration of Conformity for MiniLifts

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	MiniLift series are indoor movable and portable units which together with their approved accessories are used as sit to stand devices and for transferring users between two points.
MDR Classification	Class I; Rule I and Rule XIII
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**	2023-07-14 Kista, Sweden

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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 10993-1:2018	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	Information supplied by the manufacturer of medical device
IEC 60601-1:2005IEC 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
EN ISO 10535:2006	Hoists for the transfer of disabled persons –Requirements and test methods

Appendix II – Product Listing

Description	Article No.	Basic UDI
MiniLift160 Classic	400641436	7331769039943
MiniLift160 Classic LL	400641437	7331769039950
MiniLift160 EM	60300010	7331769032821
MiniLift160 EML	60300011	7331769032838
MiniLift160 EE	60300012	7331769032845
MiniLift160 EEL	60300013	7331769032852
MiniLift200	401100334	7331769014223

The following articles are accessories to the product family MiniLifts:

Description	Article No.	Basic UDI
ThoraxSling XS	45500003	7331769019709
ThoraxSling S	45500004	7331769014728
ThoraxSling M	45500006	7331769014322
ThoraxSling L	45500007	7331769014735
ThoraxSling XL	45500008	7331769014742
ThoraxSling XXL	45500009	7331769014759
ThoraxSling, with seat support S	45600004	7331769014766
ThoraxSling, with seat support M	45600006	7331769014339

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ThoraxSling, with seat support L	45600007	7331769014773
ThoraxSling, with seat support XL	45600008	7331769014780
ThoraxSling, with seat support, disposable, non-woven S	45690004	7331769018269
ThoraxSling, with seat support, disposable, non-woven M	45690006	7331769018276
ThoraxSling, with seat support, disposable, non-woven L	45690007	7331769018283
ThoraxSling, with seat support, disposable, non-woven XL	45690008	7331769019952
SlingBar Wrap MiniLift	70200012	7331769013714
CalfStrap	70200033	7331769011789

Revision log

Version	Date	Amendment
1.0	2010	CE DoC vs MDD 93/42/EEG
2.0	N/A	Provenance un-known
3.0	2022-02-24	Discontinued products have been removed; Revision log is added; SRN is added
4.0	2023-07-14	Review of content; Removed GMDN; Updated ISO 1041:2008 to EN ISO 20417:2021; Removed from what serial No the calf strap was introduced