

## 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 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.

<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>	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.
<b>MDR Classification</b>	Class I
<b>Registration Agency</b>	Swedish Medical Products Agency
<b>Medical Device Regulation Assessment Route:</b>	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

## 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	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6: 2010+ AMD1:2013	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
MiniLift125	400641434	07331769014216	12330
MiniLift125 LL	400641435	07331769034269	12330
MiniLift160 Classic	400641436	07331769039943	12330
MiniLift160 Classic LL	400641437	07331769039950	12330
MiniLift160 EM	60300010	07331769032821	12330
MiniLift160 EML	60300011	07331769032838	12330
MiniLift160 EE	60300012	07331769032845	12330
MiniLift160 EEL	60300013	07331769032852	12330
MiniLift200	401100334	07331769014223	12330

**The following articles are accessories to the product family MiniLifts:**

Description	Article no	Basic UDI	GMDN
ThoraxSling XS	45500003	07331769019709	40535
ThoraxSling S	45500004	07331769014728	40535
ThoraxSling M	45500006	07331769014322	40535
ThoraxSling L	45500007	07331769014735	40535
ThoraxSling XL	45500008	07331769014742	40535
ThoraxSling XXL	45500009	07331769014759	40535
ThoraxSling, with seat support S	45600004	07331769014766	40535
ThoraxSling, with seat support M	45600006	07331769014339	40535
ThoraxSling, with seat support L	45600007	07331769014773	40535
ThoraxSling, with seat support XL	45600008	07331769014780	40535
ThoraxSling, with seat support, disposable, non-woven S	45690004	07331769018269	40535
ThoraxSling, with seat support, disposable, non-woven M	45690006	07331769018276	40535
ThoraxSling, with seat support, disposable, non-woven L	45690007	07331769018283	40535
ThoraxSling, with seat support, disposable, non-woven XL	45690008	07331769019952	40535
SlingBarWrap MiniLift	70200012	07331769013714	40535
CalfStrap (Accessory for MiniLift200 as from serial no. 200001277 and for MiniLift125 as from serial no. 125001653)	70200033	07331769011789	15693

**Revision log**

Version	Date	Amendment
1.0	19/05/2021	First issue MDR compliance
2.0	25/05/2021	1 accessory (SlingBarWrap MiniLift) has been added.