


Declaration of Conformity for Belts

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.

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|--|---|
| 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 | The Belts are indoor units or soft furnishing and goods facilitating transferring of patients with minimal friction and effort. They assist in transferring, positioning and/or lifting patients in a standing, seated or supine position. Thus, reducing the risk for work related injuries to caregivers. |
| MDR Classification | Class I, Rule I |
| 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 Asal Attabipour **Position** QARA Specialist EU
Signature  **Date and Place** 2022-02-24 Kista

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 1041:2008+ A1:2013 | Information supplied by the manufacturer of medical device |
| IEC 62366-1:2015 | Medical devices - Application of usability engineering to medical devices |
| EN 12182:2012 | Assistive products for persons with disability –General requirements and test methods |
| EN ISO 10535:2006 | Hoists for the transfer of disabled persons –Requirements and test methods |

Appendix II – Product Listing

| Description | Article No | Basic UDI | GMDN |
|------------------------------|------------|----------------|-------|
| FlexiMove, nylon, 20x60 | 3012 | 07331769000912 | 40538 |
| FlexiMove, velvet, 20x60 | 3030 | 07331769000790 | 40538 |
| FlexiMove 102x43 w/4 Handles | 4011 | 07331769000332 | 40538 |
| EasyBelt, hug, XS | 6002 | 07331769021177 | 40538 |
| EasyBelt, hug, S | 6003 | 07331769021184 | 40538 |
| EasyBelt, hug, M | 6004 | 07331769021191 | 40538 |
| EasyBelt, hug, L | 6005 | 07331769021207 | 40538 |
| EasyBelt, hug, XL | 6006 | 07331769021214 | 40538 |
| EasyBelt XS, 5 handles | 6012 | 07331769000387 | 40538 |
| EasyBelt S, 7 handles | 6013 | 07331769000394 | 40538 |
| EasyBelt M, 9 handles | 6014 | 07331769000400 | 40538 |
| EasyBelt L, 11 handles | 6015 | 07331769000417 | 40538 |
| SitWalk, 140 x 13, 8 handles | 6080 | 07331769001384 | 40538 |
| FlexiGrip, 175x9, 8 handles | 6090 | 07331769000943 | 40538 |
| FlexiBelt Hug, XS | 6072 | 07331769018566 | 40538 |
| FlexiBelt Hug, Small | 6073 | 07331769018573 | 40538 |
| FlexiBelt Hug, Medium | 6074 | 07331769018580 | 40538 |
| FlexiBelt Hug, Large | 6075 | 07331769018597 | 40538 |
| FlexiBelt Hug, XL | 6076 | 07331769018603 | 40538 |
| FlexiBelt, S, 7 handles | 6023 | 07331769000424 | 40538 |
| FlexiBelt, M, 9 handles | 6024 | 07331769000431 | 40538 |
| FlexiBelt, L, 11 handles | 6025 | 07331769000448 | 40538 |
| Flexibelt, XL, 13 Handles | 6026 | 07331769000813 | 40538 |
| Readybelt, S | 16023 | 07331769002077 | 40538 |
| Readybelt, M | 16024 | 07331769002039 | 40538 |
| Readybelt, L | 16025 | 07331769002084 | 40538 |

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|----------------------------------|--------|----------------|-------|
| Positioning Belt, 17x120cm (WxL) | 9007L | 07350042260744 | 40538 |
| Positioning Belt, 20x70cm (WxL) | 9007S | 07350042260720 | 40538 |
| Positioning Belt, 17x240cm (WxL) | 9007XL | 07350042260997 | 40538 |
| Positioning Belt, 17x110cm (WxL) | 9007 | 07350042260539 | 40538 |
| Walking Belt, XXS | 6041 | 07331769013486 | 40538 |
| Walking Belt, XS | 6042 | 07331769013493 | 40538 |

The following articles are accessories to the product family Belts:

| Description | Article No. | Basic UDI | GMDN |
|-----------------|-------------|----------------|-------|
| Support Straps | 6061 | 07331769014933 | 40538 |
| Extension strap | 6091 | 07331769001957 | 40538 |

Revision log

| Version | Date | Amendment |
|---------|------------|---|
| 4.0 | 2022-02-24 | <ul style="list-style-type: none">Discontinued products are removed, new products have been addedRevision log is added |