

Declaration of Conformity for Sit to Stand

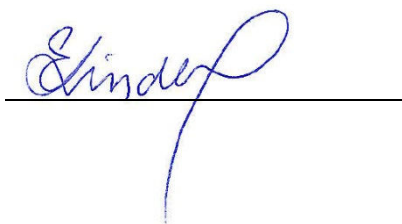
Direct Healthcare Group Sverige AB confirm the requirements specified in the Medical Device Regulation 2017/745 have been fulfilled. The undersigned has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions, and has carried out operations in accordance with these instructions.

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	Sit to Stand is intended to support a person with disability (impaired mobility, strength, balance), via self-raising mechanism, from a laying to sitting, sitting to standing positioning or sitting transfers.
MDR Classification	Class I, Rule I
Registration Agency	Swedish Medical Product Agency
Medical Device Regulation Assessment Route	Annex II of the European Medical Device Regulation (EU) 2017/745

Name Elisabet Lindberg

Position Head of Quality and Environmental Europe

Signature



Date and Place 2024-10-09, Kista

Appendix I – Applicable Standards

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

Standard	Description
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
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
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
ISO 21856:2022	Assistive products – General requirements and test methods

Appendix II – Product Listing

Description	Article no	Basic UDI
ReTurn 7400	7400	07331769012069
ReTurn7500 w open for ReturnBelt	7500i	07331769021245
ReTurn 7600	7600	07331769012090
Quick Move Transfer Aid	400801334	07331769017705
TurnSafe2	20201010	07331769022716

The following articles are accessories to the product family Sit to Stand:

Description	Article no	Basic UDI
ReTurn Belt, XXS	6031	07331769013769
ReTurn Belt, XS	6032	07331769011758
ReTurnBelt, S	6033	07331769003296
ReTurnBelt, M	6034	07331769003302
ReTurnBelt, L	6035	07331769003319
ReTurnBelt, XL	6036	07331769011765
ReTurnBelt, XXL	6037	07331769021818
ReTurnBelt, XXXL	6038	07331769021825
ReTurnBelt, disposable, S	6233	07331769030995
ReTurnBelt, disposable, M	6234	07331769031008
ReTurnBelt, disposable, L	6235	07331769031015
ReTurnBelt, disposable, XL	6236	07331769031022
Padding for leg support ReTurn (pair)	7215	07331769003326
Padding for leg support for ReTurn 7600	7216	07331769032227
ReTurn Bag, 120x55x25 cm	954	07331769021238
Heelstrap, For Return7400/Return7500	7250	07331769019846
BackSupport, for QuickMove	70200037	07331769018405