


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	<u>Roshana Eriksson</u>	Position	<u>Head of QARA EU</u>
Signature		Date and Place	<u>25/05/2021 Kista</u>

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
ReTurn 7400	7400	07331769012069	15693
ReTurn7500 w open for ReturnBelt	7500i	07331769021245	15693
ReTurn 7600	7600	07331769012090	15693
Quick Move Transfer Aid	400801334	07331769017705	15693
TurnSafe2	20201010	07331769022716	15693

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

Description	Article no	Basic UDI	GMDN
ReTurn Belt, XXS	6031	07331769013769	15693
ReTurn Belt, XS	6032	07331769011758	15693
ReTurnBelt, S	6033	07331769003296	15693
ReTurnBelt, M	6034	07331769003302	15693
ReTurnBelt, L	6035	07331769003319	15693
ReTurnBelt, XL	6036	07331769011765	15693
ReTurnBelt, XXL	6037	07331769021818	15693
ReTurnBelt, XXXL	6038	07331769021825	15693
ReTurnBelt, disposable, S	6233	07331769030995	15693
ReTurnBelt, disposable, M	6234	07331769031008	15693
ReTurnBelt, disposable, L	6235	07331769031015	15693
ReTurnBelt, disposable, XL	6236	07331769031022	15693
Padding for leg support ReTurn (pair)	7215	07331769003326	15693
Padding for leg support for ReTurn 7600	7216	07331769032227	15693
ReTurn Bag, 120x55x25 cm	954	07331769021238	15693
Heelstrap, For Return7400/Return7500	7250	07331769019846	41720
BackSupport, for QuickMove	70200037	07331769018405	15693

Revision log

Version	Date	Amendment
1.0	19/05/2021	First issue MDR compliance
2.0	25/05/2021	First page typo in the table, Directive changed to Regulation.