


## Declaration of Conformity for Sliding Boards

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>	The Sliding Boards are assistive aids intended to facilitate a caregiver's ability to support during transfer of a persons with physical disabilities with little muscular function from one place to another eg. from bed to wheelchair, from one bed to another, from wheelchair to toilet or car seat.
<b>MDR Classification</b>	Class I, Rule I
<b>Registration Agency</b>	Swedish Medical Product Agency
<b>Medical Device Regulation Assessment Route</b>	Annex II of the European 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	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

## Appendix II – Product Listing

Description	Article no	Basic UDI	GMDN
EasyGlide Oval 85x39 cm 1 Pce	5040	07331769003678	37162
EasyGlide 85x39 cm 2pcs oval	5042	07331769003685	37162
EasyGlide 60x25 cm	5060	07331769000646	37162
EasyGlide 45x20 cm	5070	07331769000653	37162
RollerSlide 175x50 cm foldable	9145	07331769002916	37162
RollerSlide 85x50 cm	9155	07331769002985	37162
RollerSlide flexi 85x50,Bend	9158	07331769003005	37162
RollerSlide flexi 175x60 cm foldable	9170	07331769021016	37162
RollerSlide flexi 85x60 cm	9175	07331769021047	37162
EasyGlide, 120x60 cm extra long	5000	07331769019976	37162
EasyGlide 60x33, foldable	5020	07331769000363	37162
EasyGlide, oval for sitting position	5045	07331769019969	37162
EasyGlide 75x33, foldable	5050	07331769000370	37162
RollerSlide light, 85X50 cm	9110	07331769008284	37162
RollerSlide, light 175x50 cm	9120	07331769004415	37162
RollerSlide, flexi 175x50 cm	9148	07331769002930	37162

The following articles are accessories to the product family sliding boards:

Description	Article no	Basic UDI	GMDN
Cover for RollerSlide 9120, 9145, 9148	9136	07331769001179	37162
Disposable Cover, For Rollerslide 175X50 Cm 9120, 9145, 914	9138	07331769000721	37162
Sliding Cover 1 Pce	9156	07331769002992	37162
Disposable Cover, For Rollerslide 85X50 cm 9110, 9155, 9158	9168	07331769003630	37162

Rollerslide Cover cm 1 Pce	9172	07331769021030	37162
RollerSlide cover 1 Pce	9177	07331769021054	37162

## 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.