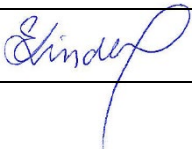


## Declaration of Conformity for Sliding Mats

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.

|  |   |
|--|---|
| <b>General Product Name</b>                            | See Appendix II   |
| <b>Legal Manufacturer</b>                              | Direct Healthcare Group Sverige AB<br>Torshamnsgatan 35<br>164 40 Kista<br>Sweden   |
| <b>Applicable standards/<br/>Common specifications</b> | As per Appendix I   |
| <b>Intended Use</b>                                    | Sliding Mats are assistive aids intended to facilitate during supine or seated transfer of a person with physical disabilities with little muscular function between two places, for example from bed to wheelchair and from wheelchair to toilet, from bed to bed. The Sliding Mats can also be used when users have difficulties turning and repositioning. |
| <b>MDR Classification</b>                              | Class I, Rule I   |
| <b>Single Registration no<br/>(SRN):</b>               | SE-MF-000014152   |
| <b>Registration Agency</b>                             | Swedish Medical Products Agency   |
| <b>Assessment Route</b>                                | Annex II of the European Medical Device Regulation (EU) 2017/745  |

|                  |   |                       |   |
|------------------|---|-----------------------|---|
| <b>Name</b>      | Elisabet Lindberg   | <b>Position</b>       | Head of Quality and Environmental<br>EU; PRRC |
| <b>Signature</b> |  | <b>Date and Place</b> | 2024-08-13 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     |
|---|-------------|---------------|
| OneWaySlide, tubular, 50 x 40 cm                | 2069        | 7331769003074 |
| OneWaySlide, tubular, 50 x 45 cm                | 2070        | 7331769000776 |
| OneWaySlide 110X30 Cm, 6 Handles                | 2074        | 7331769003913 |
| OneWaySlide 130 x 40 cm, 6 handles              | 2075        | 7331769003197 |
| OneWaySlide 130X45 Cm, 6 Handles                | 2076        | 7331769003210 |
| One Way Slide w/ 6 Handles, 130x55              | 2077        | 7331769012144 |
| Ready Slide Large - 195 X 70 Cm                 | 11210       | 7331769001971 |
| Ready Slide Medium - 110 X 70 Cm                | PH11230     | 7331769001988 |
| ReadySlide 50 X 60 cm                           | 11240       | 7331769036348 |
| Ready Slide L, With Handles195x70               | 11215       | 7331769013721 |
| Readyslide, 110x90 Extra Wide                   | 11235       | 7331769002299 |
| Readyslide 70x70                                | PH11250     | 7331769001995 |
| ReadySlide 130 x 90 cm / 51.2"x 35.4", Polyamid | PH11241     | 7331769040819 |
| ReadySlide 110 x 110 cm / 43.3"x43.3", Polyamid | 11236       | 7331769040802 |
| MoveMaster, 47 x 120 cm                         | 2090        | 7331769000462 |
| EasySlide 190x60 cm                             | 1020        | 7331769001032 |
| EasySlide 190x60 cm complete                    | 1030        | 7331769000073 |
| EasySlide 140x90, two fastening straps          | 1420        | 7331769000172 |
| EasySlide 200x90, four fastening straps         | 1470        | 7331769000202 |
| EasySlide 50x60, polyester                      | 2010        | 7331769000257 |
| EasySlide 50x60 Microfiber                      | 2020        | 7331769000271 |
| Easyslide 25x60, Polyester                      | 2015        | 7331769000264 |
| EasySlide, Microfiber 50x70 cm                  | 2021        | 7331769018818 |

| Description                     | Article No. | Basic UDI     |
|---------------------------------|-------------|---------------|
| EasySlide, disposable, 2x60 pce | 1085        | 7331769020682 |
| Easy Slide 50x60 Set, incl. co  | 2030        | 7331769000288 |
| EasySlide 100x70 cm, incl. co   | 1230        | 7331769000158 |
| EasySlide 100x70                | 1220        | 7331769000141 |
| Disposable Cover                | 1155        | 7331769001247 |

**The following articles are accessories to the product family Sliding Mats:**

| Description                               | Article No. | Basic UDI     |
|---|-------------|---------------|
| WallRack                                  | 1085        | 7331769000103 |
| Protective Cover                          | 1051        | 7331769000080 |
| Disposable Cover, For 1020, 1030 2x50 pce | 1055        | 7331769000097 |

**Revision log**

| Version | Date       | Amendment  |
|---------|------------|--|
| 5.0     | 2024-08-13 | General and periodic review: <ul style="list-style-type: none"><li>• Removed GMDN info</li><li>• Amended three article Nos due to conflicts in ERP system.</li></ul> |
| 4.0     | 2022-02-24 | <ul style="list-style-type: none"><li>• Discontinued products are removed</li><li>• Revision log is added</li></ul>  |
| 3.0     | 2021-11-18 | Alignment after MDR 2017/745 implementation  |
| 1.0-2.0 | N/A        | N/A  |