

## Declaration of Conformity for Turning Aids

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 Torshamnsgatan 35 164 40 Kista Sweden
<b>Applicable standards/ Common specifications</b>	As per Appendix I
<b>Intended Use</b>	Turning Aids are assistive aids intended to be used to facilitate the caregiver's ability to turn a disabled person with little or no muscular function in laying or sitting position.
<b>MDR Classification</b>	Class I, Rule I
<b>Single Registration no (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

**Name** Elisabet Lindberg **Position** Head of Quality and Environmental  
EU; PRRC

**Signature**  **Date and Place** 2024-08-14, 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	Articl No	Basic UDI
TurnTable	5085	7331769002770
TurnTable Soft 45cm	5086	7331769006945
TurnTable Soft 40 cm	5087	7331769012151
TopSheet 200x160 cm complete	1510	7331769003982
TopSheet 155x140 Complete	1515	7331769019129
TurnSheet 200x150 cm with buckles, complete	1586	7331769001261
TurnSheet 210x150 cm Complete	1590	7331769001131
Turn Cover for 1588, 1586	1587	7331769003487
Turnsheet 200x150 cm with buckles	1588	7331769003470
TurnSheet 200x240 cm	1589	7331769020903
TurnSheet 210x150	1592	7331769001155
TurnSheet, two parts, 200x160 cm	1597	7331769031046
AutoSlide 48 x 48 cm	8100	7331769000455
Topsheet, 144x140 Cm, complete	1520	7331769002596
TurnSheet - Pack of article 1597 and 1593	1696	7331769047764
TopSheet - Pack of articles 1515 and 1593	1697	7331769047771

The following articles are accessories to the product family Turning Aids:

Description	Article No	Basic UDI
Lockingstrap For 1420,1430,1470,1480	1599	7331769003012
EasySlide, disposable w/holder	2045	7331769020699
DisposableCover for 1220, 1230 2x90 pce	1255	7331769003494
TopSheet Lower part to 1515	1514	7331769019112

Description	Article No	Basic UDI
Lower part for 1510 140x160 cm	1509	7331769003975
Lower Part For Topsheet 1520	1519	7331769003067
Mattress Cover For 1580,1592	1583	7331769003395
MattressCover for 1590, 1592, fits 90 bed	1593	7331769001964
Mattress Cover for 1592	1594	7331769007157
Matress Cover for 120 cm bed	1595	7331769018993
Protective Cover for 2010, 2020, 2030	2051	7331769000295
Disp Cover For 2010,2020, 2030	2055	7331769000301

### Revision log

Version	Date	Amendment
6.0	2024-08-13	General review: <ul style="list-style-type: none"><li>• Removed GMDN</li><li>• Added two set articles</li><li>• Added accessories</li><li>• Corrected document properties (logo)</li></ul>
5.0	2022-05-01	Removed Art No 7215 from the accessories as this accessory belongs to product family M3 Sit to stand and is listed in 1100-M3-91.
4.0	2022-02-24	<ul style="list-style-type: none"><li>• Discontinued products are removed, new products have been added</li><li>• Revision log is added</li></ul>
3.0	2021-11-18	Alignment to MDR 2017/745
2.0	N/A	Unknown changes
1.0	N/A	Unknown changes