

Declaration of Conformity for Sliding Sheets

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.

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	Sliding sheets and Bed Covers are intended to be used for manual transfers, turning and positioning of users who have difficulties turning in bed. The Sliding Sheets enable transfer, turning or positioning to be performed without friction and without causing damage of the skin of the user.
MDR Classification	Class I, Rule I
Single Registration no (SRN):	SE-MF-000014152
Registration Agency	Swedish Medical Products Agency
Assessment Route	Annex II of the European Medical Device Regulation (EU) 2017/745

Name Elisabet Lindberg

Position

Head of Quality and Environmental
Europe; PRRC – §15; MDR 2017/745

Signature



Date and Place

Kista 2026-01-27

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
ISO 21856:2022	Assistive products – 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
WendyLett 90x200 with chip	1641CWS	7331769042462
Wendy Lett with chip	1634CH	7331769035563
WendyLett4Way 140x200, chipped	1637CH	7331769040987
WendyLett 200x90, lined, w elastics	1641CH	7331769041632
WendyLett4Way,140x190, w.handl	1657CH	7331769041649
EasyRoll Sliding sheet, 140x200cm	41902PSB	7350042260904
EasyRoll Sliding sheet, 200cm long (for 90cm bed) - D	419031D	7350042261758
Wendylett, Sliding Sheet, 100x200 Cm, White	1609	7331769002053
WendyLett 100x180 cm	1611	7331769047719
WendyLett 140x180 cm	1612	7331769047726
WendyLett 200x80 cm	1613	7331769047733
WendyLett 140x200 White	1614	7331769002060
WendyLett2Way, Drawsheet, 90x180 Cm, White	1620	7331769000929
WendyLett 140x205 cm	1621	7331769047740
WendyLett 200x205 cm	1622	7331769047757
WendyLett 215x90cm	1691	7331769047672
WendyLett 200x90, lined, w elastics	1641	7331769002718
WendyLett4Way, inco, 75x200	1648	7331769021146
WendyLett 200 x 105 with String - Bariatric	1651	7331769011963
WendyLett4Way,140x260	1652	7331769031282
WendyLett 100x220	1667	7331769021122
WendyLett 140x220	1668	7331769021139
WendyLett 100x200, lined	1629	7331769003029
Wendylett2Way 100x200, Lined	1631	7331769003043

Wendylett 140x200, Lined	1634	7331769003036
Wendylett2Way 140x200, Lined	1636	7331769003050
Wendylett4Way 140x200	1637	7331769003517
Wendylett4Way 200x190 cm	1687	7331769047665
Wendylett4Way 215x200 cm	1692	7331769047689
Wendylett 200x200, Lined	1639	7331769003166
Wendylett4Way 200x200 Cm, Grey/White Checked	1647	7331769003364
Wendylett4Way, inco,140x120	1649	7331769021153
Wendylett4Way,140x190, w.handle	1657	7331769021092
Wendylett, 200x120 tailored w.	1661	7331769031299
Wendylett 200x220, Lined	1669	7331769011970
Wendylett, 200x140 tailored w.	1671	7331769031305
Wendylean 50x60, lined	1680	7331769003173
Wendylett, 200x370	1681	7331769031602
Wendylett 140x200 cm, complete (1636&1634)	1635	7331769002541
Wendylett 140x200 cm, complete (1637&1634)	1638	7331769003999
Wendylett 140x200 inkl 4-way- comb with hoist max load 200 k	1628	7331769022730
Wendylett 100x200 cm, complete	1630	7331769002534
Wendylett & 2-Way set, 100x200	1610	7331769000899
Wendylett & 4-Way set, 200x200	1645	7331769008253
*Wendylett 140x200 white includes following	1615	7331769000905
Wendylett 200x90 inkl 4-way 140x200 cm with handles	1646	7331769040116
Wendylett & 2-Way set, 200x200	1640	7331769002558
Wendylett, sliding sheet 170 x 90 cm, 70 cm sliding area	1633	7331769041342
Wendylett 365x200	1683	7331769041380
*Wendylett 200x200 Inkl. 4 way includes following	1643	7331769004002
Wendylett inco 4-way	1658	7331769040130
Wendylett200x105cm inkl.4way 140x200 with handles	1653	7331769041953
Wendylett 2 way set, includes	1642	7331769002787
Wendylett set of 1628 and 1646	1644	7331769004019
Wendylett set of 1668 and 1636	1659	7331769041359
Wendylett set of 1667 and 1631	1663	7331769047511
Wendylett set of 1683 and 1636	1690	7331769041373
Wendylett set of 1681 and 1636	1695	7331769041366
Wendylett set of 1669 and 1636	1650	7331769045975
Wendylett set of 1668 and 1637	1655	7331769045982
EasyRoll Underpad, 120x90x180cm, 1EA=one bag 3pcs	80019	7350042262922
EasyRollSlidingSheet	41904tv	7331769041656
EasyRoll 2way Drawsheet, 100x180cm	2101	7350042260928
EasyRoll Sliding Pillow case, 50x60cm	4303	7350042263271

EasyRoll Pillow case w Barrier, 50x60cm	4304	7350042263455
EasyRoll Inco 2way Sliding sheet, 185x90cm	10991	7350042261178
EasyRoll Underpad, 150x90 cm	80018	7350042261154
EasyRoll Sliding sheet, 100cm long (for 80cm bed)	418011	7350042261581
EasyRoll Sliding sheet, 140cm long (for 80cm bed)	418021	7350042261598
EasyRoll Sliding sheet, 200cm long (for 80cm bed)	418031	7350042261604
EasyRoll Sliding sheet, 100cm long (for 90cm bed)	419011	7350042261611
EasyRoll Sliding sheet, 140cm long (for 90cm bed)	419021	7350042261628
EasyRoll Sliding sheet, 200cm long (for 90cm bed)	419031	7350042261635
EasyRoll Sliding sheet, 100cm long (for 105cm bed)	4110511	7350042261642
EasyRoll Sliding sheet, 140cm long (for 105cm bed)	4110521	7350042261659
EasyRoll Sliding sheet, 200cm long (for 105cm bed)	4110531	7350042261666
EasyRoll Sliding sheet, 100cm long (for 120cm bed)	4112011	7350042261673
EasyRoll Sliding sheet, 140cm long (for 120cm bed)	4112021	7350042261680
EasyRoll Sliding sheet, 200cm long (for 120cm bed)	4112031	7350042261697
EasyRoll Mattress protector, 105x200cm	105.200J01	7331769041434
EasyRoll 4way ProMove Inco Top w handles, 140cm	10992-5	7350042263363
EasyRoll Mattress protector, 120x200cm	120.200J01	7350042261215
EasyRoll 2way Drawsheet, 140x200cm	2101S	7350042260706
EasyRoll 4way Sliding Drawsheet, 200x200cm	4011L	7350042261383
EasyRoll 4way Sliding Drawsheet, 140x210cm	4011S	7350042260713
EasyRoll 4way Sliding Drawsheet, 150x200cm	4011S1	7350042261574
EasyRoll Sliding sheet, 100cm long (for 105cm bed)	411051P	7350042260126
EasyRoll Sliding sheet, 100cm long (for 105cm bed)	411051PS	7350042262045
EasyRoll Sliding sheet, 140cm long (for 105cm bed)	411052PS	7350042262052
EasyRoll Sliding sheet, 200cm long (for 105cm bed)	4110531R	7350042261727
EasyRoll Sliding sheet, 200cm long (for 105cm bed)	411053PS	7350042262069
EasyRoll 4way ProMove Top w handles, 200cm long (for 90cm bed)	4111LT	7350042263073
EasyRoll 4way ProMove Top w handles, 140cm long (for 90cm bed)	4111T	7350042263028
EasyRoll Sliding sheet, 100cm long (for 120cm bed)	411201PS	7350042262076
EasyRoll Sliding sheet, 140cm long (for 120cm bed)	411202PS	7350042262083
EasyRoll Sliding sheet, 200cm long (for 120cm bed)	411203PS	7350042262090
EasyRoll Sliding sheet, 100cm long (for 80cm bed)	41801PS	7350042262755
EasyRoll Sliding sheet, 140cm long (for 80cm bed)	41802PS	7350042262762
EasyRoll Sliding sheet, 200cm long (for 80cm bed)	418031R	7350042261703
EasyRoll Sliding sheet, 200cm long (for 80cm bed)	41803PS	7350042262779
EasyRoll Sliding sheet, 100cm long (for 90cm bed)	41901PS	7350042260805
EasyRoll Sliding sheet, 140cm long (for 90cm bed)	41902PS	7350042260812
EasyRoll Sliding sheet, 200cm long (for 90cm bed) - R	419031R	7350042261710
EasyRoll Sliding sheet, 200cm long (for 90cm bed)	41903PS	7350042260829

EasyRoll Sliding sheet w Barrier, 100cm long (for 90cm bed)	42901PS	7350042262212
EasyRoll Sliding sheet w Barrier, 140cm long (for 90cm bed)	42902PS	7350042262229
EasyRoll Sliding sheet, 100cm long (for 90cm bed)	4404IB	7350042262915
EasyRoll Sliding sheet w Anti-slip edge, 100cm long (for 90cm bed)	51901FAH	7350042261819
EasyRoll Sliding sheet w Anti-slip edge, 140cm long (for 90cm bed)	51902FAH	7350042261826
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 90cm bed)	519031RAH	7350042261918
EasyRoll Underpad w Sliding sheet, 80x85x180 cm	80010P	7350042263448
EasyRoll Underpad, 85x90x180 cm	80011-1	7350042261086
EasyRoll Underpad, 80x180cm	80011B	7350042263059
EasyRoll Underpad, 80x180cm	80011P	7350042263042
EasyRoll Underpad, 80x175cm	80011PI	7331769041847
EasyRoll Underpad, 90x210cm	80011PL	7350042263400
EasyRoll Underpad w Barrier, 70x190cm	80011PS	7350042263387
EasyRoll Underpad, 85x90 cm	80017-1	7350042261147
EasyRoll Underpad, 85x90 cm	80017P	7331769040635
EasyRoll Underpad, 150x90 cm	80018P	7331769040642
EasyRoll Chair pad, 45x45cm	14545GR	7331769039929
EasyRoll Chair pad, 60x60 cm	16060GR	7350042261345
EasyRoll Chair pad, 60x90 cm	16090GR	7350042261352
EasyRoll Mattress protector, 90x200cm	90.200J01	7350042261192
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 105	5110531RAH	7350042261925
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 120	5112031RAH	7350042261932
EasyRoll 4way ProMove Bottom, 140x200cm	4111B	7350042263035
EasyRoll Sliding sheet, with Chip, 100 long, for 90 cm bed	41901CH	7331769041403
EasyRoll Sliding sheet, 190cm long (for 90cm bed)	4106	7350042261468
EasyRoll 4way ProMove System, 140cm long (for 90cm bed)	41401S	7350042262564
EasyRoll Sliding sheet Anticubitus, 100cm long (for 90cm bed	45901S	7350042260416
EasyRoll 140x200 & 140x200 (419021 + 2101S)	419054	7331769041960
EasyRoll 140x200 & 140x210 (41902PS + 4011S)	419050	7331769041977
EasyRoll 140x200 & 140x210 (41902PS + 4111T)	419052	7331769041984
EasyRoll 4way ProMove System, 200cm long (for 90cm bed)	41401LS	7350042262595
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 90c	51903FAH	7350042261833
EasyRoll 4way SET, 140cm long (for 120cm bed)	41402SET	7350042263493
EasyRoll Sliding sheet w Anti-slip edge, 100cm long (for 105	511051FAH	7350042261840
Ready Sheet 195 x 75cm	PH11430	7331769002305
Ready Sheet 180x110 cm	PH11412	7331769002374
ReadyLett, sliding sheet100x200	PH11629	7331769021269
ReadyLett, sliding sheet140x200	PH11634	7331769021276
ReadyLett, sliding sheet 200x200	PH11639	7331769021283
ReadyLett, sliding sheet 90x200	PH11641	7331769021290

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PositioningCover, ULF, 200x90c	1596	7331769021535
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