


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 Asal Attabipour **Position** QARA Specialist EU
Signature  **Date and Place** 2022-02-28 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	GMDN
WendyLett 90x200 with chip	1641CWS	07331769042462	37165
Wendy Lett with chip	1634CH	07331769035563	37165
WendyLett4Way 140x200, checked	1637CH	07331769040987	37165
WendyLett 200x90, lined, w elastics	1641CH	07331769041632	37165
WendyLett4Way,140x190, w.handl	1657CH	07331769041649	37165
EasyRoll Sliding sheet, 140x200cm	41902PSB	07350042260904	37165
EasyRoll Sliding sheet, 200cm long (for 90cm bed)	419031D	07350042261758	37165
Wendylett, Sliding Sheet, 100x200 Cm, White	1609	07331769002053	37165
Wendylett 140x200 White	1614	07331769002060	37165
Wendylett2Way, Drawsheets, 90x180 Cm, White	1620	07331769000929	37165
WendyLett 200x90, lined, w elastics	1641	07331769002718	37165
WendyLett4Way, inco, 75x200	1648	07331769021146	37165
WendyLett 200 x 105 with String - Bariatric	1651	07331769011963	37165
WendyLett4Way,140x260	1652	07331769031282	37165
WendyLett 100x220	1667	07331769021122	37165
WendyLett 140x220	1668	07331769021139	37165
WendyLett 100x200, lined	1629	07331769003029	37165
Wendylett2Way 100x200, Lined	1631	07331769003043	37165
Wendylett 140x200, Lined	1634	07331769003036	37165
Wendylett2Way 140x200, Lined	1636	07331769003050	37165
WendyLett4Way 140x200, checked	1637	07331769003517	37165
Wendylett 200x200, Lined	1639	07331769003166	37165
Wendylett4Way 200X200 Cm, Grey/White Checked	1647	07331769003364	37165
WendyLett4Way, inco,140x120	1649	07331769021153	37165
WendyLett4Way,140x190, w.handle	1657	07331769021092	37165

WendyLett, 200x120 tailord w.	1661	07331769031299	37165
WendyLett 200x220, Lined	1669	07331769011970	37165
WendyLett, 200x140 tailord w.	1671	07331769031305	37165
WendyLean 50x60, lined	1680	07331769003173	37165
WendyLett, 200x370	1681	07331769031602	37165
WendyLett 140x200 cm, complete	1635	07331769002541	37165
WendyLett 140x200 cm, complete	1638	07331769003999	37165
Wendylett 140x200 inkl 4-way- comb with hoist max load 200 k	1628	07331769022730	37165
WendyLett 100x200 cm, complete	1630	07331769002534	37165
WendyLett & 2-Way set, 100x200	1610	07331769000899	37165
WendyLett & 4-Way set, 200x200	1645	07331769008253	37165
*Wendylett 140x200 white includes following	1615	07331769000905	37165
Wendylett 200x90 inkl 4-way 140x200 cm with handles	1646	07331769040116	37165
WendyLett & 2-Way set, 200x200	1640	07331769002558	37165
WendyLett, sliding sheet 170 x 90 cm, 70 cm sliding area	1633	07331769041342	37165
WendyLett 365x200	1683	07331769041380	37165
*Wendylett 200x200 Inkl. 4 way includes following	1643	07331769004002	37165
WendyLett inco 4-way	1658	07331769040130	37165
WendyLett200x105cm incl.4way 140x200 with handles	1653	07331769041953	37165
WendyLett 2 way set, includes	1642	07331769002787	37165
WendyLett set of 1668 and 1636	1659	07331769041359	37165
WendyLett set of 1667 and 1631	1663	07331769041342	37165
WendyLett set of 1683 and 1636	1690	07331769041373	37165
WendyLett set of 1681 and 1636	1695	07331769041366	37165
EasyRoll Underpad, 120x90x180cm, 1EA=one bag 3pcs	80019	07350042262922	37165
EasyRollSlidingSheet	41904tv	07331769041656	37165
EasyRoll 2way Drawsheet, 100x180cm	2101	07350042260928	37165
EasyRoll Sliding Pillow case, 50x60cm	4303	07350042263271	37165
EasyRoll Pillow case w Barrier, 50x60cm	4304	07350042263455	37165
EasyRoll Inco 2way Sliding sheet, 185x90cm	10991	07350042261178	37165
EasyRoll Underpad, 150x90 cm	80018	07350042261154	37165
EasyRoll Sliding sheet, 100cm long (for 80cm bed)	418011	07350042261581	37165
EasyRoll Sliding sheet, 140cm long (for 80cm bed)	418021	07350042261598	37165
EasyRoll Sliding sheet, 200cm long (for 80cm bed)	418031	07350042261604	37165
EasyRoll Sliding sheet, 100cm long (for 90cm bed)	419011	07350042261611	37165
EasyRoll Sliding sheet, 140cm long (for 90cm bed)	419021	07350042261628	37165
EasyRoll Sliding sheet, 200cm long (for 90cm bed)	419031	07350042261635	37165
EasyRoll Sliding sheet, 100cm long (for 105cm bed)	4110511	07350042261642	37165
EasyRoll Sliding sheet, 140cm long (for 105cm bed)	4110521	07350042261659	37165
EasyRoll Sliding sheet, 200cm long (for 105cm bed)	4110531	07350042261666	37165
EasyRoll Sliding sheet, 100cm long (for 120cm bed)	4112011	07350042261673	37165

EasyRoll Sliding sheet, 140cm long (for 120cm bed)	4112021	07350042261680	37165
EasyRoll Sliding sheet, 200cm long (for 120cm bed)	4112031	07350042261697	37165
EasyRoll Mattress protector, 105x200cm	105.200J01	07331769041434	37165
EasyRoll 4way ProMove Inco Top w handles, 140cm	10992-5	07350042263363	37165
EasyRoll Mattress protector, 120x200cm	120.200J01	07350042261215	37165
EasyRoll 2way Drawsheets, 140x200cm	2101S	07350042260706	37165
EasyRoll 4way Sliding Drawsheets, 200x200cm	4011L	07350042261383	37165
EasyRoll 4way Sliding Drawsheets, 140x210cm	4011S	07350042260713	37165
EasyRoll 4way Sliding Drawsheets, 150x200cm	4011S1	07350042261574	37165
EasyRoll Sliding sheet, 100cm long (for 105cm bed)	411051P	07350042260126	37165
EasyRoll Sliding sheet, 100cm long (for 105cm bed)	411051PS	07350042262045	37165
EasyRoll Sliding sheet, 140cm long (for 105cm bed)	411052PS	07350042262052	37165
EasyRoll Sliding sheet, 200cm long (for 105cm bed)	4110531R	07350042261727	37165
EasyRoll Sliding sheet, 200cm long (for 105cm bed)	411053PS	7350042262069	37165
EasyRoll 4way ProMove Top w handles, 200cm long (for 90cm bed)	41111LT	07350042263073	37165
EasyRoll 4way ProMove Top w handles, 140cm long (for 90cm bed)	41111T	07350042263028	37165
EasyRoll Sliding sheet, 100cm long (for 120cm bed)	411201PS	07350042262076	37165
EasyRoll Sliding sheet, 140cm long (for 120cm bed)	411202PS	07350042262083	37165
EasyRoll Sliding sheet, 200cm long (for 120cm bed)	411203PS	07350042262090	37165
EasyRoll Sliding sheet, 100cm long (for 80cm bed)	41801PS	07350042262755	37165
EasyRoll Sliding sheet, 140cm long (for 80cm bed)	41802PS	07350042262762	37165
EasyRoll Sliding sheet, 200cm long (for 80cm bed)	418031R	07350042261703	37165
EasyRoll Sliding sheet, 200cm long (for 80cm bed)	41803PS	07350042262779	37165
EasyRoll Sliding sheet, 100cm long (for 90cm bed)	41901PS	07350042260805	37165
EasyRoll Sliding sheet, 140cm long (for 90cm bed)	41902PS	07350042260812	37165
EasyRoll Sliding sheet, 200cm long (for 90cm bed)	419031R	07350042261710	37165
EasyRoll Sliding sheet, 200cm long (for 90cm bed)	41903PS	07350042260829	37165
EasyRoll Sliding sheet w Barrier, 100cm long (for 90cm bed)	42901PS	07350042262212	37165
EasyRoll Sliding sheet w Barrier, 140cm long (for 90cm bed)	42902PS	07350042262229	37165
EasyRoll Sliding sheet, 100cm long (for 90cm bed)	44041B	07350042262915	37165
EasyRoll Sliding sheet w Anti-slip edge, 100cm long (for 90cm bed)	51901FAH	07350042261819	37165
EasyRoll Sliding sheet w Anti-slip edge, 140cm long (for 90cm bed)	51902FAH	07350042261826	37165
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 90cm bed)	519031RAH	07350042261918	37165
EasyRoll Underpad w Sliding sheet, 80x85x180 cm	80010P	07350042263448	37165
EasyRoll Underpad, 85x90x180 cm	80011-1	07350042261086	37165
EasyRoll Underpad, 80x180cm	80011B	07350042263059	37165
EasyRoll Underpad, 80x180cm	80011P	07350042263042	37165

EasyRoll Underpad, 80x175cm	80011PI	07331769041847	37165
EasyRoll Underpad, 90x210cm	80011PL	07350042263400	37165
EasyRoll Underpad w Barrier, 70x190cm	80011PS	07350042263387	37165
EasyRoll Underpad, 85x90 cm	80017-1	07350042261147	37165
EasyRoll Underpad, 85x90 cm	80017P	07331769040635	37165
EasyRoll Underpad, 150x90 cm	80018P	07331769040642	37165
EasyRoll Chair pad, 45x45cm	14545GR	07331769039929	37165
EasyRoll Chair pad, 60x60 cm	16060GR	07350042261345	37165
EasyRoll Chair pad, 60x90 cm	16090GR	07350042261352	37165
EasyRoll Mattress protector, 90x200cm	90.200J01	07350042261192	37165
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 105	5110531RAH	07350042261925	37165
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 120	5112031RAH	07350042261932	37165
EasyRoll 4way ProMove Bottom, 140x200cm	4111B	07350042263035	37165
EasyRoll Sliding sheet, with Chip, 100 long, for 90 cm bed	41901CH	07331769041403	37165
EasyRoll Sliding sheet, 190cm long (for 90cm bed)	4106	07350042261468	37165
EasyRoll 4way ProMove System, 140cm long (for 90cm bed)	41401S	07350042262564	37165
EasyRoll Sliding sheet Anticubitus, 100cm long (for 90cm bed	45901S	07350042260416	37165
EasyRoll 140x200 & 140x200 (419021 + 2101S)	419054	07331769041960	37165
EasyRoll Sliding sheet, 190cm long (for 90cm bed)	4106	07350042261468	37165
EasyRoll 140x200 & 140x210 (41902PS + 4011S)	419050	07331769041977	37165
EasyRoll 140x200 & 140x210 (41902PS + 4111T)	419052	07331769041984	37165
EasyRoll 4way ProMove System, 200cm long (for 90cm bed)	41401LS	07350042262595	37165
EasyRoll Sliding sheet w Anti-slip edge, 200cm long (for 90c	51903FAH	07350042261833	37165
EasyRoll 4way ProMove System, 140cm long (for 90cm bed)	41401S	07350042262564	37165
EasyRoll 4way SET, 140cm long (for 120cm bed)	41402SET	07350042263493	37165
EasyRoll Sliding sheet Anticubitus, 100cm long (for 90cm bed	41402SET	07350042260416	37165
EasyRoll Sliding sheet w Anti-slip edge, 100cm long (for 105	511051FAH	07350042261840	37165
Ready Sheet 195 x 75cm	11430	07331769002305	37165
Ready Sheet 180x110 cm	11412	07331769002374	37165
ReadyLett, sliding sheet100x200	11629	07331769021269	37165
ReadyLett, sliding sheet140x200	11634	07331769021276	37165
ReadyLett, sliding sheet 200x200	11639	07331769021283	37165
ReadyLett, sliding sheet 90x200	11641	07331769021290	37165
PositioningCover, ULF, 200x90c	1596	07331769021535	37165

Revision log

Version	Date	Amendment
4.0	2022-02-28	<ul style="list-style-type: none"> Discontinued products are removed, new products are added Revision log is added