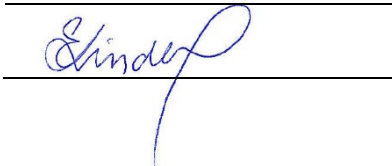


Declaration of Conformity for Sliding Sheets

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 EU; PRRC |
| Signature |  | Date and Place | Kista 2024-08-13 |

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 |
|---|------------|---------------|
| 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 140x200 White | 1614 | 7331769002060 |
| Wendylett2Way, Drawsheet, 90x180 Cm, White | 1620 | 7331769000929 |
| 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 |
| Wendylett 200x200, Lined | 1639 | 7331769003166 |
| Wendylett4Way 200X200 Cm, Grey/White Checked | 1647 | 7331769003364 |
| WendyLett4Way, inco,140x120 | 1649 | 7331769021153 |

| Description | Article No | Basic UDI |
|--|------------|---------------|
| WendyLett4Way,140x190, w.handle | 1657 | 7331769021092 |
| WendyLett, 200x120 tailord w. | 1661 | 7331769031299 |
| WendyLett 200x220, Lined | 1669 | 7331769011970 |
| WendyLett, 200x140 tailord 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 incl.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 |
| WendyLett 100x180 cm | 1611 | 7331769047719 |
| WendyLett 140x180 cm | 1612 | 7331769047726 |
| WendyLett 200x80 cm | 1613 | 7331769047733 |
| WendyLett 140x205 cm | 1621 | 7331769047740 |
| WendyLett 200x205 cm | 1622 | 7331769047757 |
| WendyLett4Way 200x190 cm | 1687 | 7331769047665 |
| WendyLett 215x90 cm | 1691 | 7331769047672 |
| WendyLett4Way 215x200 cm | 1692 | 7331769047689 |
| 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 |

| Description | Article No | Basic UDI |
|--|------------|---------------|
| 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) | 41111LT | 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 |

| Description | Article No | Basic UDI |
|--|-------------------|------------------|
| 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 |
| PositioningCover, ULF, 200x90c | 1596 | 7331769021535 |

Revision log

| Version | Date | Amendment |
|---------|------------|---|
| 7.0 | 2024-08-13 | General Updates: <ul style="list-style-type: none">• Added new sizes of WendyLett• Amended three article Nos due to conflicts in ERP system. |
| 6.0 | 2023-03-27 | <ul style="list-style-type: none">• Added a set of WendyLett |
| 5.0 | 2023-01-24 | <ul style="list-style-type: none">• Added two set of WendyLett, removed GMDN |
| 4.0 | 2022-02-28 | <ul style="list-style-type: none">• Discontinued products are removed, new products are added• Revision log is added |