



Declaration of conformity

Orange Medicals B.V.
Sluiskade 1A
9601LA Hoogezand
The Netherlands
SRN: NL-MF-000041825

Hereby declares under our sole responsibility as the legal manufacturer that the product specified below meet the essential health and safety requirements and is in conformance with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

The product(s) specified below is "technical aid for the disabled", classified as Class I medical device. The classification is based on the requirements of Rule 1 of annex VIII of the Regulation (EU) 2017/745.

| Article number | UDI | Description |
|-----------------------|-------------------|--------------------------------|
| 5015016 | (01)8718444882640 | Shower Commode Chair with legs |
| 5015011 | (01)8718444881056 | Shower Commode Wheelchair |
| 5015012 | (01)8718444881049 | Shower Commode Chair |
| 5015013 | (01)8718444882619 | Shower Commode Chair XL |
| 5015014 | (01)8718444882626 | Tilting Shower Commode Chair |
| 5015015 | (01)8718444882633 | Shower Commode Wheelchair XL |

And the associated accessories

| Article number | UDI | Description |
|-----------------------|-------------------|---|
| 5015900 | (01)8718444881612 | Cover cap for 501501X |
| 5015901 | (01)8718444881629 | Bucket for 501501X |
| 5015902 | (01)8718444881636 | Bracket footrest for 501501X |
| 5015903 | (01)8718444881643 | Single footrest for 501501X |
| 5015904 | (01)8718444881650 | Caster wheel + break for 501501X |
| 5015905 | (01)8718444881667 | Seat for 501501X |
| 5015906 | (01)8718444881872 | Brake set for 501501X |
| 5015907 | (01)8718444882091 | Single-armrest for 501501X |
| 5015908 | (01)8718444882107 | Clips for 501501X |
| 5015909 | (01)8718444882114 | Backrest for 501501X |
| 5015911 | (01)8718444882664 | Fixed set armrest, right for 501501X |
| 5015912 | (01)8718444882657 | Fixed set armrest, left for 501501X |
| 5015913 | (01)8718444882824 | Stainless Steel Axle w/ nut, 2pcs for 501501X |
| 5015914 | (01)8718444882831 | 4 leg tubes with tips and E-clips for 501501X |
| 5015915 | (01)8718444882848 | 24" wheel sets for 501501X |

Harmonised standards used for conformity

EN 1041:2008, EN 12182:2012, ISO 14971:2012, ISO 7176-3:2012, ISO 7176-8:2014 (cor. 2015-09), EN 12183:2009



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A. Sigtermans, Director

16-6-2025

Hoogezand, The Netherlands

