



DECLARATION OF CONFORMITY

WinnCare Nordic ApS. Taarnborgvej 12C, 4220 Korsoer, Denmark. SRN: DK-MF-000002147., as the manufacturer of following product/equipment declare compliance with the applicable provisions of Regulation (EU) 2017/745 of 05 April 2017 and the following standards: EN ISO 10535:2006, EN ISO 14971:2019, EN ISO 3759, EN ISO 6330 and EN ISO 5077, EN ISO 13485:2016.

Brand:



Tradename:

Ergosling

Model/Type:

- Toilet / SWL 275 kg
- Low Back / SWL 275 kg
- Standing / SWL 250 kg
- Standing 2-belt / SWL 250 kg
- Leg sling / SWL 150 kg

From serial number:

100001

Product classification:

- Product group
- Usage
- Sterility

ISO 9999:2016

12 36 21 Body-support units for hoists

Reusable medical device

Nonsterile

Classification:

MDR Class 1 in accordance with Rule 1 / 13 of Annex VIII of Regulation (EU) 2017/745

UDI number:

05740008100122, 05740008100139, 05740008100146, 05740008100153, 05740008100160, 05740008100177, 05740008100306, 05740008100313, 05740008100320, 05740008100337, 05740008100344, 05740008100351, 05740008100184, 05740008100191, 05740008100207, 05740008100214, 05740008100221, 05740008100238, 05740008100252, 05740008100269, 05740008100276, 05740008100283, 05740008100290, 05740008100115.

Korsoer, 25 May 2021

Place and date

Richard Christiansen, Technical director,
WinnCare Nordic ApS

WinnCare Nordic ApS, Taarnborgvej 12C, 4220 Korsoer, Denmark

