



DECLARATION OF CONFORMITY

Winnocare Nordic ApS. Taarnborgvej 12C, 4220 Korsoer, Denmark. SRN: DK-MF-00002147., 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:

- Universal Basic
- Universal Basic with head support
- Universal Basic, mesh
- Universal Basic with head support, mesh

SWL:

275 kg

From serial number:

100001 - 100002

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:

05740008100719, 05740008100726, 05740008100733, 05740008100740, 05740008100757, 05740008100764, 05740008100771, 05740008100788, 05740008100795, 05740008100801, 05740008100818, 05740008100825, 05740008100832, 05740008100849, 05740008100856, 05740008100863, 05740008100870, 05740008100887, 05740008100894, 05740008100900, 05740008100917, 05740008100924, 05740008100931, 05740008100948.

Korsoer, 25 May 2021

Place and date

Richard Christiansen, Technical director,
Winnocare Nordic ApS

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

