



DECLARATION OF CONFORMITY

Winnocare 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:

- Universal Comfort
- Universal Comfort with head support
- Universal Comfort, mesh
- Universal Comfort with head support, mesh

SWL:

275 kg

From serial number:

10001 - 10002

Product classification:

- Product group: ISO 9999:2016, 12 36
Body-support units for hoists
- Usage: Reusable medical device
- Sterility: Nonsterile

Classification:

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

UDI number:

574000810059, 574000810060, 574000810061, 574000810062, 574000810063, 574000810064, 574000810065, 574000810066, 574000810067, 574000810068, 574000810069, 574000810070, 574000810199, 574000810095, 574000810096, 574000810097, 574000810098, 574000810099, 574000810100, 574000810200, 574000810101, 574000810102, 574000810103, 574000810104, 574000810105, 574000810106.

Korsoer, 18 May 2021

Place and date

Richard Christiansen, Technical director,
Winnocare Nordic ApS

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

