



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:

- Universal Hammock, mesh
- Universal Hammock with head support, mesh

- Universal Amputee
- Universal Amputee with head support

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:

05740008100368, 05740008100375, 05740008100382, 05740008100399, 05740008100405,
05740008100412, 05740008101983, 05740008100429, 05740008100436, 05740008100443,
05740008100450, 05740008100467, 05740008100474, 05740008100481, 05740008100498,
05740008100504, 05740008100511, 05740008100528, 05740008100535, 05740008100542,
05740008100559, 05740008100566, 05740008100573, 05740008100580.

Korsoer, 25 May 2021

Place and date

Richard Christiansen, Technical director,
WinnCare Nordic ApS

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

