



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 10535:2007 (EN 60601-1:2006, EN 60601-1-2:2015, EN ISO 14971:2019, EN ISO 13485:2016):

Brand:

WINCARE

Tradename:

ErgoTrainer

Model/Type:

Weight relief system

From serial number:

ERT-10105

Product classification:

- Product group:
- Usage:
- Sterility:

ISO 9999:2016

04 48 07 Assistive products for exercising gait pattern
Reusable medical device
Nonsterile

Classification:

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

Basic UDI-DI

5740008109001U3

UDI number:

05740008101891, 05740008101907,
05740008101914, 05740008101921.

Korsoer, 29 January 2024

Place and date

Richard Christiansen, Technical director,
WinnCare Nordic ApS

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

