CE

WINNCARE Nordic

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

Brand:	ergolet
Tradename:	Mobile Flex
Model/Type:	2-post system, 4-post system
From Serial number:	MFB-210012, MFC-210012, MF4-210009
UDI number:	574000810183, 574000810184, 574000810185, 574000810186, 574000810187, 574000810188
Product classification:	ISO 9999:2016, 12 36 18 Stationary free-standing hoists
-Product group:	Mobile Flex
-Usage	Reusable medical device
-Sterility	Nonsterile
Classification:	MDR Class 1 in accordance with Rule 1 / 13 of Annex VIII of Regulation (EU) 2017/745

Korsoer, 19 May 2021
Place and date

Richard Christiansen, Technical director,
Winncare Nordic ApS

ISO 13485 BUREAU VERITAS Certification

ISO 9001 BUREAU VERITAS Certification