



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:	WIN CARE
Tradename:	Mobile Flex
Model/Type:	Mobole gantry
From Serial number:	MFB-210012, MFC-210012, MF4-210009
Product classification:	ISO 9999:2016
-Product group	12 36 18 Stationary free-standing 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
Basic UDI-DI:	5740008104001SY
UDI number:	05740008101839, 05740008101846, 05740008101853, 05740008101860, 05740008101877, 05740008101884

Korsoer, 01 February 2024
Place and date


Richard Christiansen, Technical director,
WinnCare Nordic ApS

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

