




DECLARATION OF CONFORMITY (EN)

WinnCare Nordic ApS, Taarnborgvej 12C, 4220 Korsoer, Denmark. SRN: DK-MF-000002147., as the manufacturer of following product/equipment, declares sole responsibility for the issuance of the Declaration of Conformity with the applicable provisions of Regulation (EU) 2017/745 of 05 April 2017 and the following standards: ISO 10535:2021 (IEC 60601-1-2:2014, 60601-1-2:2014, ISO 14971:2019, ISO 13485:2016):

Brand:	WIN CARE
Tradename:	LUNA® X5
Model/Type:	Luna X5
From serial number:	LX5-240001
Intended use:	Ceiling hoist for transferring people with reduced mobility in care institutions, home care and hospitals
Product classification:	ISO 9999:2022
- Product group:	12 36 12 Stationary hoists fixed to walls, floor or ceiling
- Usage:	Reusable medical device
- Sterility:	Non sterile
Classification:	MDR Class 1 in accordance with Rule 1 / 13 of Annex VIII of Regulation (EU) 2017/745
Basic UDI-DI:	5740008101014SL
UDI number:	05740008102836

Korsoer 24 Februar 2025

Place and date


Richard Christiansen, Technical director,
WinnCare Nordic ApS.

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

