



DECLARATION OF CONFORMITY (EN)

WinnCare Nordic ApS, Taarnborgvej 12C, 4220 Korsør, Denmark. SRN: DK-MF-000002147, as the manufacturer of the following product/equipment, declares sole responsibility for the issuance of the Declaration of Conformity with the applicable provisions of Regulation (EU) 2017/745 of 5 April 2017 and the following standards: ISO 10535:2021 (IEC 60601-1:2014, 60601-1-2:2014, ISO 14971:2019, ISO 13485:2016):

Trade Name:	WinnCare
Device Model:	Luna IPX4
Device Name:	Ceiling Hoist
From serial number:	LUN-130001
Intended use:	Ceiling hoist for transferring people with reduced mobility in care institutions, home care and hospitals
Product classification:	ISO 9999:2016
- Product group:	12 36 12 Stationary hoists fixed to walls, floor or ceiling.
- 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:	5740008101001SB

Korsoer, 04 June 2025

Place and date


Richard Christiansen, Technical director,
WinnCare Nordic ApS.

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

