



## 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:



Tradename:

Luna IPx4  
Luna/200 Kg/Strap  
Luna/275 Kg/Strap  
Luna/200 Kg/Bayonet  
Luna/275 Kg/Bayonet  
Luna/200 Kg/Bayonet/2ch.  
Luna/275 Kg/Bayonet/2ch.  
Luna/200 Kg/Room to room/Strap  
Luna Twin/275–400 Kg/Bayonet  
Luna Twin set/275–400 Kg  
Luna SKY/200 Kg

From serial number:

LUN-130001

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

UDI number:

05740008101372, 05740008101389, 05740008101396, 05740008101402, 05740008101426, 05740008101433, 05740008101440, 05740008101457, 05740008101464, 05740008101471.

Korsoer, 25 May 2021

Place and date

Richard Christiansen, Technical director,  
WinnCare Nordic ApS

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

