EU Declaration of Conformity

The EU declaration of conformity is issued under the sole responsibility of the manufacturer

Manufacturer:	*Rehab-Care dk ApS*	
Address:	*Avnvej 10, 7400 Herning, Denmark*	
Trade name(-s):	rehab-care®	
SRN:	**DK-MF-000039192**	

Product Name:	**Stoleløfter**		
Type / Model:	**ST-24000/ST-25000**	**Basic UDI-DI:**	05745000344468
Intended purpose:	**Stoleløfter**		
Class / rule / annex: *(EU 2017/745)*	Class I, Active device rule 13, Conformity assessment annex II and III		

The device covered by this EU declaration of conformity is in conformity with the following Regulation and harmonized standards:

Regulation EU 2017/745 of the European Parliament and of the Council of 5. April 2017 on Medical devices (MDR)

Harmonized standards used:

EN ISO 14971:2019	Application of risk management to medical devices
EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes.
EN 60601-1:2006/ A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 62366-1:2015	Application of usability engineering to medical devices
IEC 12100:2010	General principles for design – Risk assessment and risk reduction.

DK-7400 Herning 19-12-2023
Place and Date

Martin Gam, CEO , Rehab-care dk ApS

rehab-care.dk®

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