Faaborg Rehab Technic Aps

Faaborg, 2021-05-26.

CE Declaration of conformity.

The conformity rating is carried out with Annex IV of the MDR regulation.
Regulation (EU) 2017/745OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices Class 1.

We: Faaborg Rehab Technic ApS.
Registered place of business
Smedemestervej 9
5600 Faaborg

Hearby declare that the following hoists are CE - marked complying with the:
DS/EN ISO 10535:2007 Hoists for the transfer of disabled persons – Requirements and test methods. The product specified on the product list below is "technical aid for the disabled" classified as Class 1, medical device.
The classification is based on the requirements of Rule 1 of annex VIII, of the Regulation (EU)2017/745.The CE marking has been affixed on the product to Annex V of the Regulation (EU)2017/745

PRODUCT LIST.	Passive	Basic UDI DI.
Careline KingVL200/250		57400120KingVL2003KT3

The hoists comply with essential requirements in annex 1, also comply with the requirements described in: Requirements for mobile hoists edition no. 89.04 (12 27 03 mobile hoists with slings and liftingstraps.)
Described by: Rådet for tekniske tiltak for funksjonshæmmede, Norway, Handicappinstitutet, Sweden, Dansk Hjælpemiddel Institut, Denmark.
The hoists comply with the requirements in DS/EN ISO 10535:1998 or DS/ EN ISO 10535:2007-02-07 2. edition hoists for the transfer of disabled persons- Requirements and test methods comply to Class I.

Allan Hansen

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