

oetac*

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EC DECLARATION OF CONFORMITY

Hereby declare that the following product(s):

Molift Quick Raiser 1 Molift Quick Raiser 2 Molift Quick Raiser 2+

and that the accessoires used only together with this product, are CE marked and complies with the Council Directive concerning medical devices 93/42/EEC, and according to this classified as medical equipment Class I.

Annex IX rules that all non invasive devices are in Class I.

Expiration date: 25th April 2024

Product classification:

12 ASSISTIVE PRODUCTS FOR PERSONAL MOBILITY12.36 ASSISTIVE PRODUCTS FOR LIFTING PERSONS

12.36.04 MOBILE HOISTS FOR TRANSFERRING A PERSON IN STANDING POSITION

Usage:

Reusable medical device

Sterility:

Non

Classification:

MDD Class 1

Molift Quick Raiser 1,2,2+ is manufactured in conformity with the following national or international standards that also might implement a harmonised standard:

EN 10535:2006 Hoists for the transfer of disabled persons - Requirements and test methods

EN 14971:2007 Medical equipment - Risk analysis

EN 60601-1 Medical electrical equipment

EN 60601-1-2 Electromagnetic compatibility

EN 60601-11 Medical electrical equipment used in the home healthcare environment

RoHS 2 - Directive 2011/65/EU

Title:

Quality Manager Åsmund Amlien

Name: Company:

Etac AS, Etac Supply Gjøvik

07.02.2019

Date

Signature

Asmund Antien