To whom it may concern

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Alu Rehab MDR compliance

The European Medical Device Regulation (EU 2017/245) is coming into force on May 26th, 2021. Due to the corona crisis the date for MDR has been delayed by one year – from 2020 to 2021.

Through the Norwegian EFTA agreement with EU – Norway is an associated member of EU and follows the European rules and regulations. Alu Rehab is a Norwegian manufacturer and follow those rules and regulations.

The purpose of MDR is to ensure safety for the end user of the product by traceability and transparency. Alu rehab is putting great effort into becoming compliant with MDR and is well en route. Alu Rehab has already a well-functioning quality system for management of medical devices according to ISO 13485:2016 which is yearly audited by TÜV SÜD Germany.
The quality system is being extended with MDR requirements and we expect to have this in place by May 2020.

Netti wheelchairs produced by Alu Rehab, are risk class 1 (low risk) and are all in compliance with MDD (Medical Device Directive) Each wheelchair model has a valid certificate according to EN 12183:2014. Each certificate will be renewed one by one according to MDR in due time before each certificate expire. The renewal of a certificate is completed after extensive testing at TÜV SÜD according to the wheelchair standard EN 12183.
In MDR a transition period from MDD certificates to MDR certificates is granted and will be closed by end of 2024.

Each wheelchair is followed by a Declaration of Conformity. This document is regularly renewed when substantial alterations in design, production or other aspects are changed. Each wheelchair is followed by a user manual containing all required and necessary information for safe and correct adaptation and use. The user manual is renewed at least by every renewal of the wheelchair certificate.

A substantial part of MDR is registering information about the medical devices brought to the European market in the central EudaMed database. This database is delayed by 2 years and is expected to be released in 2022. Alu Rehab will continue registering our medical devices in the existing Norwegian database until Eudamed is released.

Alu Rehab is identifying each individual Netti wheelchair with the unique serial number placed on each wheelchair. With this number we can trace each chair in our IT system. The system will be adapted to EudaMed requirements as soon as possible.

For Alu Rehab AS

Sigrun Peerstøe-Kotthaus

Product Safety Responsible