To whom it may concern

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Alu Rehab MDR compliance

The European Medical Device Regulation (EU 2017/245) came into force May 26th, 2021.

Through the Norwegian EFTA agreement with EU – Norway is an associated member of EU and follows the European rules and regulations. Alu Rehab AS 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 pr today in compliance with MDR. Alu Rehab has a quality system for management of development and production of medical devices according to ISO 13485 which is yearly audited by TÜV SÜD Germany.
The quality system is extended with MDR requirements and is in place since May 2021.

Netti wheelchairs produced by Alu Rehab, are risk class 1 (low risk) and is in compliance with MDR (Medical Device Regulation). Each wheelchair model has a valid certificate according to EN 12183. Each certificate is renewed one by one according to MDR in due time before each certificate expires. The renewal of a certificate is completed after extensive testing at TÜV SÜD according to the wheelchair standard EN 12183.

Each wheelchair is followed by a Declaration of Conformity and CE mark. 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 manuals and the Declarations of Conformity are updated according to MDR and are published on our homepage.

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 2023. 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 a unique serial number placed on each wheelchair. With this number we can trace each chair in our IT system. The labelling system is updated according to MDR. Each wheelchair is labelled with QR code and UDI-DI and UDI-PI numbers.

Summing up: Alu Rehab AS is in compliance with MDR and the Alu Rehab Netti products are CE marked and are fulfilling MDR requirements.

For Alu Rehab AS

Mike Dongelmans
Product Safety Responsible