CE

Netti®

EC Declaration of Conformity

for

Class 1 Medical Devices MDR (EU)2017/745

Alu Rehab AS
Bedriftsveien 23
4353 Klepp Stasjon, Norway

SRN (single registration number) NO-MF-000014047

Netti Dynamic System and accessories

EMDN	Y122103 Push wheelchair, Y122106 Rear self propelled wheelchair, Y122499 Accessories
Basic UDI-DI	704764NettiDynamicSys9Y
	Conforms to the Medical Device Regulation MDR (EU)2017/745

Intended purpose: Dynamic wheelchair for severely disabled youth and adult persons. The wheelchair enables ADL function and mobility, varying seating positions and comfort during long time seating, allowing for more independence and improvements of quality of life.

Alu Rehab AS uses the procedures for the CE-labelling of Netti products according to Regulation MDR 2017/745 Annex IV

The following standards and the standards they request are used:

ISO 21856:2022	Technical aids for disabled persons. General requirements and test methods.
EN 12183:2014	Manual wheelchairs – Requirements and test methods.
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices.
EN 1021-2:2014	Assessment of the ignitability of upholstered furniture.

This declaration of conformity is issued under the sole responsibility of Alu Rehab AS.
We hereby declare that the medical device(s) specified above meet the provision of the Regulation MDR (EU) 2017/745 for medical devices. This declaration is supported by the Quality System approval according to ISO 13485:2016 issued by TÜV SÜD.
All supporting documentation is retained at the premises of the manufacturer.

Klepp Stasjon 2023-06-01

Björn Carlzon
Managing Director

inspire joy of life

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