



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 Vision and accessories

GMDN 41630 Wheelchair, attendant driven, collapsible

Basic UDI-DI 704764NettiVisionGG

Conforms to the Medical Device Regulation MDR (EU)2017/745

Intended purpose: Wheelchair for severely disabled youth and adult persons. The wheelchair enables 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:

EN 12182:2012 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 (EU) MDR 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, 2022-10-03



Björn Carlzon
Managing Director



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