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 Cushions and accessories

GMDN 11100	Wheelchair Seat cushions
GMDN 62720	Medical cushion cover
Basic UDI-DI	704764NettiUno4C, 704764NettiSmartZ3, 704764NettiStabilDB, 704764NettiSuperstabilSM, 704764NettiKyphotic8E, 704764NettiUno4C, 704764NettiSit3V, 704764NettiSSitSV, 704764NettiSSuperstabil7N Conforms to the Medical Device Regulation MDR (EU) 2017/745.
Intended purpose:	Wheelchair cushions. The cusions are designed to provide support, comfort and assistance to the occupant of a wheelchair typically by improving posture, providing back and/or side support, relieving stress points. This is a reusable device.

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 1021-2: 2014	Furniture, Assessment og ignitability of upholstered furniture. Ignition source match-flame.
EN 10993-5:2009	Biological evaluation of medical devices (Part 5: test for in-vitro cytotoxicity)
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.

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. All supporting documentation is retained at the premises of the manufacturer.

Klepp Stasjon 2023-01-16

Björn Carlzon
Managing Director

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