Combination Agreement

This agreement between Alber GmbH and Alu Rehab AS (the Parties) outlines that the integration of Alber medical devices with various Alu Rehab wheelchair models (referred to as Products) complies with the MDR Medical Device Regulation EU 2017/745 regarding product combination.

The medical equipment/devices manufactured by Alber in the table below can be combined with the equipment/devices manufactured by Alu Rehab AS in the table below, provided that the combination is carried out in a professional manner and in accordance with the restrictions of both manufacturers, as indicated in the user manuals and installation instructions, provided by the manufacturers.

	Alber Device								
Wheelchair Model **Device Name**	e-ifx E35/E36	e-motion M25 & Duo Drive	viamobil V14	viamobil V25	via GO V24	e-pilot P15	smoov O10	Scalamobil S35	**Remarks**
Netti V family	✓	✓	–	✓	✓	–	–	–	Including: Base, All-round
Netti III family	✓	✓	–	✓	✓	–	–	✓	Including: HD, XHD, XXHD
Netti 4U family	✓	✓	–	✓	✓	–	–	✓	Including: CE, CE Plus, CED, CEDXL, Base
Netti Dynamic family	✓	✓	–	–	–	–	–	–	Including: IIIHD, 4U CED, 4U Base

The combination of **ALBER** aids with **Alu Reha AS** wheelchairs may only be carried out by authorized and trained personnel in accordance with the ALBER assembly instructions. This training is provided either by a local training course at Alber or by a person authorized to provide training.
Alber restrictions (e.g. seat width, maximum user weight) have to be observed (check compatibility online with Alber Dealer Information Pool / DIP before starting the process of ordering and combining).

Observe the product limitations and instructions for use given in the user manuals of all equipment mentioned in this combination agreement. Machining, bending, welding, or bracing of safety relevant components is not permitted. Exceptions are permitted in accordance with the manufacturer's installation instructions.

ALBER shall be responsible for the verification activities, including the relevant documentation relating to the combination. The relevant documentation shall be made available to Alu Rehab AS in a timely manner upon request.

Alber GmbH has performed the required risk evaluation of the Alber GmbH medical devices and Alu Rehab AS has performed the risk evaluation for Netti wheelchair families according to MDR (Medical Device Regulation (EU)2017/745). The parties have each risk evaluated the combination of Alber medical devices mounted to the different manual Netti wheelchairs. Both parties confirm that there are no increased risks by the combination of the Netti wheelchairs and Alber GmbH medical devices. The Products are both CE-marked devices.

Each Party has the product liability for its medical device. The Parties jointly have the product liability for the Products in combination. Both parties shall communicate planned changes to their device as far as the combination may be affected.

All external communication, in particular communication to the competent authorities regarding the combination, shall first be communicated between the parties. In general, communication to the authorities shall be made by the manufacturer of the device which has caused an adverse event. Support for requests from authorities and requests for investigation of adverse events shall be provided by both parties within the timeframe specified by the authority or manufacturer.

This agreement is valid from date of signature and is subject to three months' notice for termination.
If regulatory requirements should change or if constructional changes are made to the products, each of the parties shall evaluate whether this affects the validity of this agreement and inform the other party without any delay of such circumstances.
This Combination Agreement was issued in duplicate and signed duly by authorised representatives.

ALBER GmbH Vor dem Weißen Stein 14 72461 Albstadt Germany	**Alu Rehab AS** Bedriftsveien 23 4353 Klepp stasjon Norway

Date: 31.05.2024

Bernd Engels
Director Product Management
Authorized Officer

Date:

Mikel M. Dongelmans
Product- and Development Manager