Product Combination Agreement

The combination is handled as a special adaptation for each new user and is to be performed in close cooperation with the medical professional therapist.

This agreement between **Benoit Systèmes** and **Alu Rehab AS** (the Parties) outlines that the integration of Benoit Systèmes medical devices with various Netti 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 Benoit Systèmes 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.

Wheelchair Model Device Name	BENOIT SYSTEMES **LIGHT DRIVE 2.1**	BENOIT SYSTEMES LIGHT ASSIST 2.1	BENOIT SYSTEMES LIGHT DRIVE PLUS 2.1	**Remarks**
Netti III	✓	✓	Contact us	
Netti III EL	✓	✓	Contact us	
Netti III HD	✓	✓	Contact us	
Netti III HD Dynamic	✓	✓	Contact us	
Netti III XHD	✓	✓	Contact us	
Netti III XXHD	✓	✓	Contact us	
Netti 4U Base	✓	✓	Contact us	
Netti 4U Base Dynamic	✓	✓	Contact us	
Netti 4U CE	✓	✓	Contact us	
Netti 4U CE Plus	✓	✓	Contact us	
Netti 4U CED	✓	✓	Contact us	
Netti 4U CED Dynamic	✓	✓	Contact us	
Netti 4U CED XL	✓	✓	Contact us	
Netti V	✓	✓	Contact us	
Netti S	✓	✓	Contact us	
Netti Dynamic S	✓	✓	Contact us	
Netti mini	✓	✓	Contact us	

The combination of Benoit Systèmes aids with Alu Reha AS wheelchairs may only be carried out by authorized and trained personnel in accordance with the Benoit assembly instructions. This training is provided either by a local training course at Benoit Systèmes or by a person authorized to provide training.

Benoit Systèmes restrictions (e.g. seat width, maximum user weight) are listed in compatibility chart on the Benoit Systèmes website (https://benoitsystemes.com/en/documentation.php). This chart should be consulted before starting the process of ordering and combining.

Machining, bending, welding, or bracing of safety relevant components is not permitted. Exceptions are permitted

in accordance with the manufacturer's installation instructions.

Benoit Systèmes 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.

Benoit Systèmes has performed the required risk evaluation of the Benoit Systèmes 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 Benoit Systèmes 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 Benoit Systèmes medical devices. The Products are both CE-marked devices.

The parties are responsible for possible limitations in use, instructions for installation and use, and required documentation for the medical device(s) listed above. *Alu Rehab AS* pledges to inform *Benoit Systèmes* about any design wheelchair changes which may affect the safety and or function of the Products in combination and vice verca.

Each Party has the product liability for its medical device. The Parties jointly have the product liability for the Products in combination.

The Parties renounce responsibility for a combination if not assembled according to each Parties installation and instructions for use (IFU).

IFU for the combination is established. The IFU for the combination and for each separate product must be handled to the user and attendant and must be read carefully. *The IFU contains important information and warnings to make the products to be safe to use for the user.*

Provided the above conditions are met, the manufacturers hereby declare that the combination of the products also meets the requirements according to the standards.

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.

Should any incident occur with the combination of the products described in this agreement, a copy of this agreement should be added to the report to the Authorities.

This agreement is valid from date of signature and is subject to three months' notice for termination.
This agreement shall be valid for an indefinite period as from this execution. However, it can be terminated by either of the parties within 30 days given notice in writing.

This Combination Agreement was issued in duplicate and signed duly by authorized representatives.

Benoit Systèmes 7 rue du Pont 21450 BILLY-LES-CHANCEAUX FRANCE	**Alu Rehab AS** Bedriftsveien 23 4353 Klepp stasjon Norway

Date: 22/05/2025

Director Product Management
Authorized Officer

Date: 10-06-2025

Mikel M. Dongelmans

Product- and Development Manager

Alu Rehab AS
Bedriftsveien 23
NO-4353 Klepp stasjon
Norway
NO 941 181 953 MVA