Combination Agreement

between

Party 1:
Alu Rehab AS
Bedriftsvegen 23
4353 Klepp Stasjon
Norway

and

Party 2:
AAT Alber Antriebstechnik GmbH
Ehestetter Weg 11
72458 Albstadt
Germany

as manufacturers of the devices listed in the Product List

1.) Duration

This agreement starts with the date of the Signature below for an indefinite period and can be ended by each of the both parties at the end of each month, subject to a 30-day notice period.

2.) Products and Combination Conditions

This Combination Agreement refers to the products listed in the table "Product List" (listed under point 6) and their mutual compatibility. The compatibility has been recognized and demonstrated by the contracting parties in the manner prescribed by the laws and regulations and the applicable (harmonized) standards.

The products listed in the table "Product List" (Point 6) can be combined under the following conditions:

2.1. The necessary AAT-fittings must be fitted onto the basic frame of the wheelchair.
Should it be necessary to place the fittings on other parts of the wheelchair, the specific locations must be determined individually and agreed upon by both parties.

2.2. Constructional changes to the wheelchairs:
Should it be necessary to add or remove parts, or make any other changes to the wheelchair frame, these modifications must be approved by the wheelchair manufacturer.
Machining, bending, welding or bracing on any safety relevant components are not allowed.

2.3. The assembly instructions in the product manuals must be followed
If any special fittings are required for specific wheelchairs, the design and manufacturing therefor must be agreed upon by both parties. The approved fittings must be accompanied by specific assembly instructions.

2.4. Technical reservations concerning the combination must be specified
If one of the parties is of the opinion, that a combination requires specific equipment to be fitted to a wheelchair (e.g. wheels with specific dimensions), this must be agreed by both parties and recorded in specific fitting instructions.

2.5. The combined motor unit must not restrict any functions or adjustments of the wheelchair
Certain modifications to the original adjustment capabilities of the wheelchair are acceptable provided they do not affect safety issues.

2.6. Any further reservations regarding the combination must be agreed by both parties

2.7. If used products are to be used for the combination, they first must be tested for reusability according to the respective instructions.

3.) Active information obligation

The Parties shall promptly inform and assist each other with all necessary information when...

- significant changes were made
- a regulatory authority or a report from field reveals a significant nonconformity with the regulatory requirements according to the products
- possible recalls of the products have potential impact on mutual compatibility

4.) In case of incidents

In the event of an incident involving a combined product, the parties will inform each other and assist in a professional manner in assessing the safety relevance and investigating the incident. The parties will provide each other with all relevant information.

5.) Declaration:

Both parties named above declare under own responsibility that the combined products to which this declaration relates, do have an own Declaration of Conformity in compliance with the Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017.

In particular, the clauses relating to the combination of Medical Devices:

MDR Annex I, Chapter II "Requirements regarding Design and Manufacture":

14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimize all possible risks, such as misconnection.

23.4 Information in the instructions for use:

(q) for devices intended for use together with other devices and/or general purpose equipment:

- information to identify such devices or equipment, in order to obtain a safe combination, and/or
- information on any known restrictions to combinations of devices and equipment

MDR Annex II, Technical Documentation:

1.1 Device description and specification:

(h) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it

6.2 Additional information required in specific cases:

(g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

6.) Product List:

Product list of compatible devices:

Party 1 The following wheelchairs:	Party 2 The following "add-on drive units" or "stairclimbers":
Netti V	V-MAX²
	v-max
	SOLO
	SOLO+
	SERVO

7.) Signatures:

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

Alu Rehab

Date: 11-12-2024
Name: Mike Dongelmans
Function: Product Development manager.

AAT Alber Antriebstechnik GmbH
Ehingen · Ehestetter Weg 11
72458 Albstadt
Tel. +49 74 31 12 95 - 0
Fax +49 74 31 12 95 - 35

AAT Alber Antriebstechnik GmbH

Date: 06.12.2024
Name: Daniel Mohr
Function: QMB / PRRC