## **Product Combination agreement**

TA Service A/S

Centervej syd 2 4733 Tappernøje Danmark Alu Rehab AS

Bedriftsvegen 23 4353 Klepp Stasjon Norway

as manufacturers of:

TA Service electrical Wheelchairs:

TA IQ FWD, TA IQ MWD, TA IQ RWD TA IQ FWD Stand-up, TA Indoor Wave Netti Seating System -Wheelchair seat and back cushions: Netti Uno seat, Netti Sit, Netti UNO back, Netti Smart, Netti Stabil, Netti Superstabil Netti Kyphotic

hereby declare that the above-mentioned products can be combined under the following conditions:

- 1) The Velcro fixation on the cushions must fit with Velcro fixation on the wheelchairs. The Velcro system is meant to fasten the cushions to the wheelchair to secure the user of the wheelchair from sliding and to keep a stable posture position.
- 2) It is the responsibility of the person fitting the wheelchair to the user to secure that the cushions are correct ergonomic positioned for the wheelchair user.
- 3) The user instruction for each product must be read carefully.

  The user instruction contains important information and warnings to make the products to be safe to use for the user.
  - This agreement between TA Service A/S and Alu Rehab AS (the Parties) states that the
    combination of the Alu Rehab AS Postural Support Devices and TA Service wheelchairs in
    combination (Products) meets the MDR Medical Device Regulation EU 2017/745 concerning
    product combination.
  - 2. TA Service A/S has performed the required risk evaluation of the TA Service wheelchairs and Alu Rehab has performed the risk evaluation for Netti seating system according to MDR (Medical Device Regulation (EU)2017/745). Both parties confirm that there are no increased risks by the combination of the Netti cushions and TA Service wheelchairs.
  - 3. The Products are both separately CE-marked devices and registered separately at a notified body.
  - 4. TA Service A/S is responsible for the risk analysis of the combination of the medical device(s) listed above. 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 TA Service A/S about any design changes to its Seating System components which may

affect the safety and or function of the Products in combination. TA Service A/S pledges to inform Alu Rehab A.S about any design changes to its electrical wheelchairs which may affect the safety and or function of the Products in combination.

- **5.** Each Party has the product liability for its medical device. The Parties jointly have the product liability for the Products in combination.
- **6.** The Parties renounce responsibility for a combination if not assembled according to each Parties installation and use instructions.
- 7. This agreement is valid from today and is subject to three months' notice for termination.
- 8. This document has been drawn up in two copies of which each Party has taken one.

The medical devices listed have been tested in combination in accordance with the Medical Device Regulation (EU) 2017/745.

TA Service A/S

Signature Pond Deckey

Title Product Planeira

Place / Date Tapperage

Alu Rehab AS

Signature

a d

Place / Date Capp

2022-11-22



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