Product Combination agreement

Rehatechnik Heymer GmbH

Von-Siemens-Straße 15a 59757 Arnsberg Tyskland

Alu Rehab AS

Bedriftsvegen 23 4353 Klepp Stasjon Norway

as manufacturers of:

Electrical pushing aid Heymer RadUn2S Wheelchair Netti AdaptPro and Netti Dynamic AdaptPro

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

- A) The combination is handled as a special adaptation for each new user. The adaptation to the user is to be performed in close cooperation with the medical professional therapist i.a. choice of dynamic gas spring strength, movement range etc.
- 1. This agreement between Rehatechnik Heymer GmbH and Alu Rehab AS (the Parties) states that the combination of the Heymer RadUn2S and the wheelchair Netti AdaptPro and Netti Dynamic AdaptPro in combination (Products) meets the MDR Medical Device Regulation EU 2017/745 concerning product combination.
- 2. Rehatechnik Heymer GmbH has performed the required risk evaluation of the Heymer RadUn2S and Alu Rehab AS has performed the risk evaluation for Netti AdaptPro and Netti Dynamic AdaptPro according to MDR (Medical Device Regulation (EU)2017/745). The parties have each risk evaluated the combination of Heymer RadUn2S mounted to the for Netti AdaptPro and Netti Dynamic AdaptPro with its fixing system.

 Both parties confirm that there are no increased risks by the combination of the Heymer RadUn2S and the Netti AdaptPro and Netti Dynamic AdaptPro.
- 3. The Products are both separately CE-marked devices.
- The parties are jointly responsible for 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 Rehatechnik Heymer GmbH about any design changes wheelchair Netti AdaptPro and Netti Dynamic AdaptPro components which may affect the safety and or function of the Products in combination. Rehatechnik Heymer GmbH pledges to inform Alu Rehab AS about any design changes to its Heymer RadUn2S which may affect the safety and or function of the Products in combination.
- Each Party has the product liability for its medical device. The Parties jointly have the product liability for the Products in combination.
- 6. The combination described shall be mounted as a Heymer RadUn2S kit delivered from Rehatachnik Heymer GmbH for the German market by skilled staff at Rehatechnik Heymer GmbH and for the international sales by skilled staff at Alu Rehab AS Klepp or Alu Rehab ApS Ry according

- to the instructions and manuals provided for the combination and product information for each product.
- 7. The Parties renounce responsibility for a combination if not assembled according to each Parties installation and instructions for use (IFU).
- 8. 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.
- 9. This agreement is valid from today and is subject to three months' notice for termination.
- 10. This document has been drawn up in two copies of which each Party has taken one.

Rehatechnik Heymer GmbH

Signature

Ti+la

Place / Date

Alu Rehab AS

Signature

Title Do

Place / Date 26/06

Alu Rehab AS
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