

Product Combination Agreement

Meyra GmbH

and

Alu Rehab A.S

Meyra-Ring 2
D-32689 Kalletal-Kalldorf

Bedriftsvegen 23
NO-4353 Klepp Stasjon

Germany

Norway

As manufacturers of

Meyra Wheelchairs

Netti Velcro back sling kit
88772 (BxH 35-50 x35 cm)

44993 (BxH 50-75 x35 cm)

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

- 1) The Netti Velcro back sling kit is to be mounted to the Meyra wheelchairs, securing tight fit between the wheelchair chair-back tubes and the sling side pockets.
- 2) *The Netti Velcro system is meant to fasten the wheelchair back cushions to the wheelchair to secure the user a stable back support.
The Netti Velcro System allows adjustments of the horizontal straps to hold and support the back cushion and allowing individual back curve shape – to be adjusted to the user and thereby optimizing the back support.*
- 3) It must be assured that the correct size is chosen.
The back cushions are depending on support from the back sling to work properly when exposed for forces from the user leaning against it.
- 4) It is the responsibility of the person adjusting the Netti Velcro back-sling kit to the user to secure that the adjustments of the support of the back is done in a way that serves the user most beneficial.
- 5) It is the responsibility of the person fitting the wheelchair to the user to secure that the pivot point of the wheelchair / balance is not moved in a critical position.
As the cushions vary in thickness, design, height, width and length, it may change the properties of the wheelchair from its original specifications and risk assessment for the use of the wheelchair which needs to be considered by the caretaker doing the fitting
- 6) In addition to the user manual of Meyra wheelchair will be enclosed the user manual of the Netti Velcro back sling kit.
- 7) This agreement between *Alu Rehab AS* and *Meyra GmbH* (the Parties) states that the combination of the *Meyra GmbH wheelchairs listed, equipped with Netti Velcro back sling kit* (Products) meets the Medical Device Regulation MDR (EU) 2017/745 class 1 concerning product combination.
- 8) The Products are both separately CE-marked devices.



- 9) The Parties are responsible for possible limitations in use, instructions for installation and use, risk analysis, and required documentation of the medical device(s) listed above. *Alu Rehab AS/ Meyra Netti* pledges to inform *Meyra GmbH* about any design changes to its Netti Velcro sling kit devices which may affect the safety and or function of the Products in combination. *Meyra GmbH* pledges to inform *Alu Rehab A.S* about any design changes to its wheelchairs which may affect the safety and or function of the Products in combination.
- 10) Each Party has the product liability for its medical device. The Parties jointly have the product liability for the Products in combination.
- 11) The Parties renounce responsibility for a combination if not assembled and adjusted according to Parties installation and use instructions.

This document has been drawn up in two copies of which each Party has taken one.

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.

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

This document has been drawn up in two copies of which each Party has taken one.
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 contract and inform the other party without any delay of such circumstances.

This agreement shall be valid for an indefinite period as from this execution. However, it can be terminated by either of the parties by 60 days given notice in writing.

Kalletal / Klepp Stasjon

Dato: November 2020

Dato: November 2020

Meyra GmbH

Alu Rehab AS / Meyra Netti



Friedrich Kottmeier
Executive Director of Purchasing/Production/Logistic



Kjetil Gausel
CEO