



Combination Agreement

The below mentioned products are in principle appropriate to be combined with the below mentioned **ALU REHAB** products provided that the combination is made expertly and according to the restrictions of both manufacturers. The restrictions can be asked at the manufacturers.

SUNRISE MEDICAL product	ALU REHAB product
Empulse R20	Netti 4u, CE, CE Plus, CED, Base Netti III; Netti III HD, Netti XHD &
	Dynamic functions (sw 350 – 600mm)
	Netti S (sw 350,400 mm)
	Netti Dynamic S (sw 350,400)

Please note that mounting and limitations has to be effected according to the Sunrise Medical and ALU REHAB mounting instructions and restrictions by authorized and skilled staff only based on the provided mounting instructions and user information.

The maximum values and restrictions (e.g. user weight) mentioned in the user manual of both manufacturers must be observed.

If a crash tested wheelchair is to be used as a seat in a vehicle. The pushing device R20 must be removed and stored safely elsewhere in the car.

Constructional changes to the wheelchair e.g. machining, bending, welding or bracing on any safety relevant components are not allowed. Should it be necessary to add or remove parts (standard Alu Rehab accessories are excluded), or to make any changes to the wheelchair frame, such modifications must be approved by the wheelchair manufacturer.

The Netti wheelchairs and the pushing device R20 mentioned in this agreement are CE marked and conform to the directive and standard of 93/42 EEC Medical Device Class 1 and MDR 2017/745.

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.

Each party has the product liability for its medical device. The parties jointly have the product liability for the product combination.

Provided the above conditions are met, the manufacturers hereby declare that the combination of the products also meet the requirements according to the directive and standard of 93/42 EEC Medical Device Class 1 and MDR 2017/745.

If regulatory requirements should change or if constructional changes are made to the products, each of the parties shall evaluate whether or not this affects the validity of this agreement and inform the other party without any delay of changes which may affect the safety and or function of the products in combination.

In case of any incident with the combination of the products a copy of this agreement should be added to the report to the authorities.

The agreement shall be valid for an indefinite period of time as from this execution. The agreement is valid from today and it is subject to three month notice for termination.

The combination agreement has been drawn up in two copies of which each party has taken one.

Authorized representatives of the parties have executed this agreement.

SUNRISE MEDICAL **Europe** Kahlbachring 2-4 D 69254 Malsch/Heidelberg Germany

Malsch, 5.02.2020

ALU REHAB AS

Bedriftsvegen 23 NO-4353 Klepp ST Norway

Klepp ST., 5.02.2020

Authorized by

Gerd Weis

(Senior test engineer)

Sigrun Peerstøe-Kotthaus

(Product safety responsible)

SUNRISE Sunnise Medical GmbH Kanhachning 2-4
D-69254 Masch/Heidelberg Dieforn +49 7253 980 0
Www.SunriseMedical.de Telefax +49 7253 980 111