
EU DECLARATION OF CONFORMITY

Manufacturer

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|----------|--|
| Name: | Rehadapt GmbH |
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This declaration of conformity is issued under the sole responsibility of the manufacturer:

Object of the declaration

| | |
|-------------------|---|
| Product family: | Rehadapt wheelchair mounts |
| Description: | Mounts for assistive technology devices, switches and consumer electronics attached to the frame of wheelchairs and intended to be used by the wheelchair occupant. |
| Basic UDI-DI: | ++B896WheelchairMountsQB |
| Products covered: | See Annex 1 |
| Intended purpose: | See Annex 2 |
| Classification: | Class 1 medical devices |

The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Medical Device Regulation (MDR) (EU) 2017/745

References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

- EN ISO 13485:2021: Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2019 Application of risk management to medical devices

Additional information

N/A

Signed for and on behalf of:



16.9.25

Michael Jakobi
CEO

Annex 1 to EU Declaration of Conformity

List of medical devices belonging to the product family "Rehadapt wheelchair mounts"

| Art. Nr. | Name | UDI-DI |
|-----------|--------------------------------------|-------------------|
| 11.3100 | Monty 3D | *+B8961131000_* |
| 11.3211 | Monty 3D QuickShift | *+B8961132110+* |
| 11.3311 | Monty 3D QuickShift Sturdy | *+B8961133110%* |
| 11.3312 | Monty 3D Plus | *+B89611331200* |
| 11.4312 | Monty 3D Plus HD | *+B89611431201* |
| 11.2211 | Monty 3D TT | *+B8961122110/* |
| 11.2312 | Monty 3D TT Plus | *+B8961123120%* |
| 11.5311 | Monty 3D Curved M | *+B89611531101* |
| 11.6312 | Monty 3D Curved L | *+B89611631203* |
| 11.7312 | Monty 3D Curved XL | *+B89611731204* |
| 11.8016 | Monty 3D CoMoveIT Smart | *+B89611801606* |
| 13.2011 | Hybrid 3D Universal UDS | *+B8961320110/* |
| 13.2015 | Hybrid 3D Universal SLS | *+B89613201501* |
| 13.3211 | Hybrid 3D Short UDS | *+B89613321100* |
| 13.3311 | Hybrid 3D Short UDS Sturdy | *+B89613331101* |
| 13.3215 | Hybrid 3D Short SLS | *+B89613321504* |
| 13.3315 | Hybrid 3D Short SLS Sturdy | *+B89613331505* |
| 13.4211 | Hybrid 3D Long UDS | *+B89613421101* |
| 13.4311 | Hybrid 3D Long UDS Sturdy | *+B89613431102* |
| 13.4215 | Hybrid 3D Long SLS | *+B89613421505* |
| 13.4315 | Hybrid 3D Long SLS Sturdy | *+B89613431506* |
| 14.2211 | Light 3D TT UDS | *+B89614221100* |
| 14.2015 | Light 3D TT SLS | *+B89614201502* |
| 14.2075 | Light 3D MagicArm SLS | *+B89614207508* |
| 14.3211 | Light 3D QuickShift UDS | *+B89614321101* |
| 14.3215 | Light 3D QuickShift SLS | *+B89614321505* |
| 14.2415 | Light 3D Headrest 1-Switch | *+B89614241506* |
| 14.2515 | Light 3D Headrest 1-Switch Flex | *+B89614251507* |
| 14.3415 | Light 3D Headrest 2-Switch | *+B89614341507* |
| 14.3515 | Light 3D Headrest 2-Switch Flex | *+B89614351508* |
| 11.3100CM | Custom Monty 3D | *+B896113100CM0T* |
| 11.3211CM | Custom Monty 3D QuickShift | *+B896113211CM0W* |
| 11.3241CM | Custom Monty 3D Swing Away QS | *+B896113241CM0Z* |
| 11.3311CM | Custom Monty 3D QuickShift Sturdy | *+B896113311CM0X* |
| 11.3341CM | Custom Monty 3D Swing Away QS Sturdy | *+B896113341CM0-* |
| 11.3230CM | Custom Monty 3D Fold-down Right | *+B896113230CM0X* |
| 11.3220CM | Custom Monty 3D Fold-down Left | *+B896113220CM0W* |
| 11.3312CM | Custom Monty 3D Plus | *+B896113312CM0Y* |
| 11.3342CM | Custom Monty 3D Swing Away Plus | *+B896113342CM0.* |
| 11.4312CM | Custom Monty 3D Plus HD | *+B896114312CM0Z* |

| | | |
|-----------|------------------------------------|--------------------|
| 11.4342CM | Custom Monty 3D Swing Away Plus HD | *+B896114342CM0* |
| 11.2211CM | Custom Monty 3D TT | *+B896112211CM0V* |
| 11.2312CM | Custom Monty 3D TT Plus | *+B896112312CM0X* |
| 11.6312CM | Custom Monty 3D Curved | *+B896116312CM0.* |
| 13.3211CM | Custom Hybrid 3D UDS | *+B896133211CM0Y* |
| 13.3311CM | Custom Hybrid 3D UDS Sturdy | *+B896133311CM0Z* |
| 13.3215CM | Custom Hybrid 3D SLS | *+B896133215CM0* |
| 13.3315CM | Custom Hybrid 3D SLS Sturdy | *+B896133315CM0\$* |
| 14.2211CM | Custom Light 3D TT UDS | *+B896142211CM0Y* |
| 14.2015CM | Custom Light 3D TT SLS | *+B896142015CM0-* |
| 14.3211CM | Custom Light 3D QuickShift UDS | *+B896143211CM0Z* |
| 14.3215CM | Custom Light 3D QuickShift SLS | *+B896143215CM0\$* |
| 14.2415CM | Custom Light 3D TT 1-Switch SLS | *+B896142415CM0/* |

Annex 2 to EU Declaration of Conformity

Intended purpose of the product family "Rehadapt wheelchair mounts"

Description

Mounting systems intended to support assistive technology devices to be used by persons seating on a chair (e.g. wheelchair) or lying on a bed.

Intended purpose

Rehadapt **wheelchair mounts** are modular mechanical systems with the purpose of fixating adaptive technology devices to mobility aids and hold them in position for use.

The wheelchair mounts are composed of tubes or rods, joints and connectors. While connecting to the payload device with an interface that allows for quick detachment of the piece of adaptive technology, the joints and tubes enable flexible and precise positioning of the device, to ensure the user's operation of the device in spite of possible motor impairments or specific device requirements. Rehadapt wheelchair mounts also employ mechanisms to move the mount and the device out of the way of the beneficiary, if necessary.

They are to be attached to a wheelchair using a Rehadapt frame clamp. The quick connection interface mates with a semi-permanently fixated device attachment plate or spigot manufacturer by Rehadapt or the device manufacturer.

Rehadapt wheelchair mounts are not life-sustaining nor life-supporting and can be used wherever the wheelchair is used, either indoors or outdoors.

All necessary technical specifications (including dimensions and load capacity) are included in the respective assembly instructions and product description.

Indication(s)

Wheelchair users who rely on adaptive technology to communicate (AAC), access ICT, operate environmental control units or require additional wheelchair input (e.g. switches or joysticks).

Contraindication(s)

none

Intended patient group

Patients with hereditary, congenital, degenerative or acquired movement disorders, specifically in conjunction with limitations in communication; or patients with limitations in verbal speech.

Conditions include, but are not limited to:

- Cerebral Palsy
- Neuromuscular diseases such as ALS, SMA, or MS
- Acquired Brain Injuries such as Stroke, TBI or aneurysms
- Rett or Angelman syndrome, or other severe multiple disabilities
- Autism Spectrum Disorders
- Injuries or amputations

Intended users

Rehadapt products are intended to be installed by a qualified distributor and to be operated by the care personal of the patient (family, caregiver, teacher, therapist, nursing staff, etc.). In some cases, it might be operated by the patients themselves if they possess sufficient motor control to do so.