# EU DECLARATION OF CONFORMITY

## Manufacturer

| | |
|---|---|
| Name: | **Rehadapt GmbH** |
| Address: | Heinrich-Hertz-Str. 104 |
| | 34123 Kassel, Germany |
| SRN: | **DE-MF-000008141** |
| Phone: | +49 561 220 717 0 |
| Fax: | +49 561 220 717 99 |
| Email: | officeteam@rehadapt.com |

This declaration of conformity is issued under the sole responsibility of the manufacturer:

## Object of the declaration

| | |
|---|---|
| Product family: | **Rehadapt table mounts** |
| Description: | Mounts to place assistive technology devices, switches or consumer electronics on top or clamped to tables and other surfaces. |
| Basic UDI-DI: | **++B896TableMountsTC** |
| 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 table mounts"

| Art. Nr. | Name | UDI-DI |
|---|---|---|
| 12.1602 | TS-XL | *+B89612160201* |
| 12.1653 | TS-DC | *+B89612165307* |
| 12.1652 | TS-GO | *+B89612165206* |
| 12.1650 | TS-UC | *+B89612165004* |
| 12.1655 | TS-UC SLS | *+B89612165509* |
| 12.1660 | TS-FT | *+B89612166005* |
| 12.1647 | TS-AT | *+B8961216470A* |
| 12.1665 | TS Cradle Kickstand | *+B8961216650A* |
| 12.1700 | TC | *+B89612170000* |
| 12.1760 | ClampOnMount | *+B89612176006* |
| 12.1770 | ClampOnMount-Dual-SC | *+B89612177007* |
| 12.1730 | TC-OH | *+B89612173003* |
| 12.1735 | TC-OH Light | *+B89612173508* |
| 12.1740 | TC-OH HD | *+B89612174004* |
| 12.1783 | TC L3D 1QS UDS | *+B8961217830B* |
| 12.1780 | TC L3D 1QS SLS | *+B89612178008* |
| 12.1721 | TC L3D FM UDS | *+B89612172103* |
| 12.1722 | TC L3D FM SLS | *+B89612172204* |
| 12.1784 | TC L3D 2QS UDS | *+B8961217840C* |
| 12.1781 | TC L3D 2QS SLS | *+B89612178109* |
| 12.1775 | TC L3D MagicArm SLS | *+B8961217750C* |
| 12.1785 | TC L3D 3QS UDS | *+B8961217850D* |
| 12.1782 | TC L3D 3QS SLS | *+B8961217820A* |
| 14.5052 | L3D MC 2QS Switch Mount | *+B89614505206* |
| 14.5552 | L3D MC 2QS Switch Mounting Kit | *+B8961455520B* |
| 14.5553 | L3D MC 2QS Flex Switch Mounting Kit | *+B8961455530C* |
| 14.5554 | L3D MC 1QS Universal Phone Mounting Kit | *+B8961455540D* |
| 14.5555 | L3D MC 2QS Switch Mounting Kit | *+B8961455550E* |
| 14.5560 | L3D MC 2QS Switch Mounting Kit Flex | *+B8961455600A* |
| 12.1724 | Magnitude Flex | *+B89612172406* |
| 12.1787 | Magnitude 360 | *+B8961217870F* |
| 15.1041 | Magnitude One | *+B89615104101* |

11.9.2025

# Annex 2 to EU Declaration of Conformity

## Intended purpose of the product family
## "Rehadapt table mounts"

### Description
Mounts to place assistive technology devices, switches or consumer electronics on top or clamped to tables and other surfaces.

### Intended purpose
Rehadapt **table mounts** are mounting systems that are either self-standing on a table top (table stand) or semi-permanently attached to it (table clamp). They serve the purpose of holding adaptive technology devices in position for use.

While connecting to the payload device with an interface that allows for quick detachment of the piece of adaptive technology, the table mount allows flexibly for precise positioning of the device, to ensure the user's operation of the device in spite of possible motor impairments or specific device requirements. The quick connection interface mates with a semi-permanently fixated device attachment plate or spigot by Rehadapt or the device manufacturer.

Rehadapt table mounts are not life-sustaining nor life-supporting and can be 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)
Persons who rely on adaptive technology to communicate (AAC), access ICT, or operate environmental control units.

### 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

### 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.