

## EU DECLARATION OF CONFORMITY

### Manufacturer

Name:	<b>Rehadapt GmbH</b>
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This declaration of conformity is issued under the sole responsibility of the manufacturer:

### Object of the declaration

Product family:	<b>Rehadapt floorstands</b>
Description:	Self-standing mounts intended that support assistive technology devices to be used by persons seating on a chair (e.g. wheelchair) or lying on a bed.
Basic UDI-DI:	<b>++B896FloorstandsK5</b>
Products covered:	See Annex 1
Intended purpose:	See Annex 2
Classification:	<b>Class 1 medical devices</b>

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 Jakob  
CEO

## Annex 1 to EU Declaration of Conformity

### List of medical devices belonging to the product family "Rehadapt floorstands"

Art. Nr.	Name	UDI-DI
17.1055	FS EcoLock	*+B89617105508*
17.1070	FS EcoFloat	*+B89617107005*
17.1080	FS EcoFloat Light	*+B89617108006*
17.1072	FS EcoFloat HD	*+B89617107207*
17.1050	FS TeleLock	*+B89617105003*
17.1052	FS TeleLock QP	*+B89617105205*
17.1073	FS TeleFloat	*+B89617107308*
17.1074	FS TeleFloat QP	*+B89617107409*
17.1083	FS TeleFloat Light	*+B89617108309*
17.1084	FS TeleFloat Light QP	*+B8961710840A*
17.1061	FS VarioLock	*+B89617106105*
17.1063	FS VarioLock QP	*+B89617106307*
17.1093	FS VarioLock QP Plus	*+B8961710930A*
17.1065	FS VarioFloat	*+B89617106509*
17.1066	FS VarioFloat QP	*+B8961710660A*
17.1085	FS VarioFloat Light	*+B8961710850B*
17.1086	FS VarioFloat Light QP	*+B8961710860C*
17.1102	FS PentaLock Eco	*+B89617110201*
17.1100	FS PentaLock Tele	*+B8961711000%*
17.1172	FS PentaFloat Eco	*+B89617117208*
17.1170	FS PentaFloat Tele	*+B89617117006*
17.1400	FS Mini	*+B89617140002*
17.1401	FS Mini SLS	*+B89617140103*
17.1410	FS Mini HD	*+B89617141003*
17.1411	FS Mini SLS HD	*+B89617141104*

## Annex 2 to EU Declaration of Conformity

### Intended purpose of the product family "Rehadapt floorstands"

#### Description

Self-standing mounts 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 **floorstands** are self standing stands consisting of a chassis, a column and an articulated arm. They are intended to hold adaptive technology devices in position to be used for a beneficiary who sits, stands or lies in front of or under the stand.

While connecting to the payload device with an interface that allows for quick detachment of the piece of adaptive technology, the adjustable articulated arm and the column allow for 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. The quick connection interface mates with a semi-permanently fixated device attachment plate or spigot by Rehadapt or the device manufacturer.

Rehadapt floorstands are not life-sustaining nor life-supporting but they are intended to be used solely indoors.

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
- 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.