
EU DECLARATION OF CONFORMITY

Manufacturer

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| Name: | Rehadapt Engineering GmbH & Co. KG |
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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 |
| Article numbers: | The products encompassed in this product family are listed in the table on page 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 2017/745

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

- EN ISO 13485:2016: 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:



Ulrich K Ehlert
CEO

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* |
| 13.3211 | Hybrid 3D Short UDS | *+B89613321100* |
| 13.3215 | Hybrid 3D Short SLS | *+B89613321504* |
| 13.4211 | Hybrid 3D Long UDS | *+B89613421101* |
| 13.4215 | Hybrid 3D Long SLS | *+B89613421505* |
| 14.2211 | Light 3D TT UDS | *+B89614221100* |
| 14.2015 | Light 3D TT SLS | *+B89614201502* |
| 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* |
| 11.3311CM | Custom Monty 3D QuickShift Sturdy | *+B896113311CM0X* |
| 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* |
| 11.4312CM | Custom Monty 3D Plus HD | *+B896114312CM0Z* |
| 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* |
| 13.3215CM | Custom Hybrid 3D SLS | *+B896133215CM0_* |
| 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\$* |