



# EU Declaration of Conformity

|                                   |   |
|-----------------------------------|---|
| Manufacturer                      | R82 A/S<br>Parallevej 3<br>DK-8751- Gedved<br>Denmark<br>Phone no.: +45 79655888<br><a href="http://www.etac.com">www.etac.com</a>  |
| SRN                               | DK-MF-000000772   |
| Statement                         | This declaration of conformity is issued under the sole responsibility of the manufacturer.<br>The device(s) covered by this declaration of conformity is/are in conformity with EU Regulation 2017/745 on medical devices. |
| Basic UDI-DI                      | 57072920933074F   |
| EMDN                              | Y1299   |
| Intended Purpose                  | Assistive device for toileting, washing, bathing and showering for persons with disabilities  |
| Device name(s)                    | Manatee   |
| Parts covered in this declaration | Separate list available upon request.   |
| Risk class of the device          | Class I, Rule 1   |
| Harmonized/Established Standards  | Separate list available upon request  |
| Place                             | Gedved, Denmark   |
| Date of issue                     | 2025-12-09  |
| Name and function                 | Claus Riis, QA/RA Manager   |

A handwritten signature in blue ink that reads 'C. Riis'.

Signature, on behalf of Manufacturer