# EU Declaration of Conformity

**Product Name:** Soft Tilt 3
**Manufacturer:** Careturner A/S, Silovej 16-18, DK-2690 Karlslunde
**Single registration number (SRN):** DK-MF-000020149
**Basic UDI:** 5745000569CARETURNERBT

This declaration of conformity is issued under the sole responsibility of Careturner A/S.

Applied harmonized standards, common specifications, national standards, or other normative documents:

| | |
|---|---|
| DS/EN ISO 21856:2022 | Assistive products - General requirements and test methods. |
| DS / EN 60601-1: 2005 | Medical electrical equipment. Part 1: General safety and essential functional requirements.<br>(Incl. Corr. 1: 2008, Corr. 2: 2008, AC: 2013 A1: 2013)<br>All parts of the standard exclusive parts excepted / changed in DS / EN 60601-2-52: 2010. |
| DS / EN 60601-2-52: 2010 | Medical electrical equipment. Part 2-52: Particular requirements for basic safety and essential performance of hospital and<br>care beds for medical use.<br>(Incl. AC: 2011 and A1: 2015)<br>Points: 201.8 Electrical hazards, 201.9.2.2.2 Gaps, 201.9.2.3.1 Unintended movement, 201.9.8 Support System (relevant parts), 201.11.6.5.101 Ingress of water, 201.11.6.6 Cleaning and disinfection, 201.11.8 Interruption of the power supply, 201.15.3.4.1 Hand-held ME equipment. |

We ensure and declare that:

1. The product is in conformity with the Medical Device Regulation 2017/745 (MDR).
2. The product is classified in Class I.
3. Planning and preparation are done in accordance with company quality system in accordance with the provisions of the Regulation and follows applicable requirements of DS/EN ISO 13485:2016/AC:2018.

Karlslunde 19th of August 2025

***Michael Kock***
CEO

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