EU Declaration of Conformity

Product Name: Careturner / Soft Tilt
Manufacturer: Careturner A/S, Lyskær 8B, 2730 Herlev, Denmark

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 12182: 2012	Assistive products for persons with disabilities - General requirements and test methods.
DS / EN 60601-1: 2005	Medical electrical equipment. Part 1: General safety and essential functional requirements. (Incl. Corr. 1: 2008, Corr. 2: 2008, AC: 2013 A1: 2013) 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 care beds for medical use. (Incl. AC: 2011 and A1: 2015) 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.

Herlev 11th of February 2022

Michael Kock
CEO

Careturner A/S
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