GDV Technology A/S
Værkstedsgården 15, st. th.
DK-2620 Albertslund

EC Declaration of Conformity
Careturner by GDV Technology A/S

GDV Technology A/S, Værkstedsgården 15, st. th., 2620 Albertslund, Denmark, hereby certify that the product meets the essential requirements defined in the Medical Device Directive standards:

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

Albertslund 18'th of December 2019

Michael Kock
CEO

GDV Technology A/S