

EU Declaration of Conformity

with the Medical Device Regulation (MDR) 2017/745

We,

Wolturnus A/S, Skalhuse 31, 9240 Nibe, Denmark - DK-MF-000025274

Name and Address of Manufacturer – Single Registration Number (SRN)

hereby, under our sole responsibility declare, that the product

Fatbike

Category Name

with model names and reference

Basic UDI-DI: 57138250217N

Model
Fatbike

is in conformity with the Medical Device Regulation (MDR) 2017/745 as class I medical devices based on Annex VIII and the following common specifications (CS) and standards

DS/EN ISO 14971:2019, ISO 13485:2016

Standards

The intended purpose: The Wolturnus Fatbike is an electric handcycle designed for individuals with mobility impairments and intended for off-road use on various terrains, including snow, gravel, sand, and mud. It features oversized tires for enhanced stability and an adjustable seat and backrest for personalized fit. Fatbike is equipped with the Wing Back ILSA system, ensuring optimal support and comfort during rides.

This EU declaration of conformity was written according to Annex 4 in MDR, and all supporting documentation is retained at the premises of the manufacturer.

Manufacturer

March 31, 2025 - Nibe

*Date and
place of issue*

Peter Libak, CEO

*Name and position of
authorized person*



*Signature of
authorized person*