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

Buzzard

Category Name

with model names and reference

Basic UDI-DI: 57138250257W

Model
Buzzard

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 Buzzard is a handbike designed for individuals with functional impairments and intended for training and exercise. It is an ideal model for beginners, as both the backrest and crank position can be adjusted to ensure optimal and individualized user adaptation.

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	Peter Libak, CEO	
Date and place of issue	*Name and position of authorized person*	*Signature of authorized person*