WOLTURNUS
Wheelchairs built for freedom

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

Roadrunner

Category Name

with model names and reference

Basic UDI-DI: 57138250247U

Model
Roadrunner

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

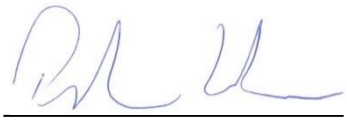
DS/EN ISO 14971:2019, ISO 13485:2016

Standards

The intended purpose: The Wolturnus Roadrunner is a running bike designed for individuals with functional impairments, intended for high-performance exercise and road racing. Roadrunner is developed for competition but can also be used for daily training and mobility. Its lightweight and aerodynamic frame ensures optimal speed, stability, and efficient power transfer. Roadrunner can be individually adjusted with customizable components to provide the best ergonomic seating position and performance.

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*