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

Racebike

Category Name

with model names and reference

Basic UDI-DI: 57138250207L

Model
Racebike
Racebike K

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 Racebike is a handbike designed to deliver maximum performance for handcyclists who are unable to walk or have mobility impairments. Racebike is intended for individual use and can be operated by the user via the hand pedals, both indoors and outdoors. Through advanced design, the Racebike is engineered to optimize speed, stability, and aerodynamics.

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*