

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

Antaras

Category Name

with model names and reference

Basic UDI-DI: 57138250227Q

Model
Antaras
Antaras Junior

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 Antaras is a handbike designed for individuals with mobility impairments and intended for sports, exercise, and recreational use on both roads and cycling paths. It combines comfort and performance with a stable, adjustable frame that ensures a customized and ergonomic seating position. Antaras is designed for individual use and operated by the user via hand pedals, enabling an active lifestyle and effective training.

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*