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

Amasis

Category Name

with model names and reference

Basic UDI-DI: 57138250237S

Model
Amasis
Amasis Skiing Chair

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 Amasis is a racing wheelchair designed for individuals with mobility impairments, intended for sport and exercise. The frame is constructed to be extra stiff and robust, ensuring maximum stability and durability under intense use. The smaller drive rings are selected to optimize power transfer, making it easier for the user to accelerate and achieve higher speeds. This design feature enhances control, maneuverability, and performance, making the Amasis ideal for competition and training. Amasis can also be used for ski training outside the season, and with a higher and more upright seating position, the chair is optimized for propulsion with ski poles and in winding terrain, making it suitable for training outside the snow season.

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*