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

Ski

Category Name

with model names and reference

Basic UDI-DI: 57138250267Y

Model
Ski Sledge

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

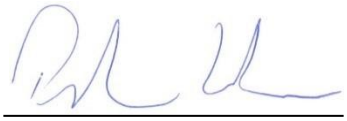
DS/EN ISO 14971:2019, ISO 13485:2016

Standards

The intended purpose: The Wolturnus Ski Sledge is a specialized seat designed for skiing, enabling individuals with disabilities to participate in the sport. It provides a stable, ergonomic, and secure seating position, ensuring optimal support during activity. The design promotes proper weight distribution and a handbrake to enhance control and comfort. Engineered to withstand the dynamic forces associated with skiing, the Ski Sledge is suitable for both recreational training and competitive use.

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*