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

Dancing

Category Name

with model names and reference

Basic UDI-DI: 571382501872

Model
Dancing

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 Dance wheelchair is a sports wheelchair used for dancing by individuals with reduced mobility. Dance is designed to optimize mobility, stability, and quick directional changes while dancing. The rear axle is moved forward to increase weight on the rear wheels, while added camber enhances stability and prevents tipping during fast turns. To counter the risk of tipping backward, an anti-tip is used, allowing movement even when engaged.

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*