

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

Tennis

Category Name

with model names and reference

Basic UDI-DI: 57138250167V

Model
Tennis

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 Tennis wheelchair is a sports wheelchair used for playing tennis and badminton by individuals with reduced mobility. Tennis is designed to optimize mobility, stability, and quick directional changes during competitive play. The cambered wheel angle and low center of gravity of the Tennis ensure maneuverability and stability. The tennis wheelchair is designed with a narrow front end to provide extra space for swinging a racket. Additionally, it is equipped with knee support, allowing the user to stretch forward without losing stability or control.

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*