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

Rugby

Category Name

with model names and reference

Basic UDI-DI: 57138250157T

Model
Rugby Attack
Rugby Defence

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 Rugby wheelchair is a sports wheelchair used for playing rugby by individuals with reduced mobility. Rugby is designed to optimize mobility, stability, and quick directional changes during competitive play. The cambered wheel angle and low center of gravity of the Basket ensure maneuverability and stability. The wheelchair features reinforced bumpers and side guards, enhancing its durability and resistance to intense impacts during gameplay.

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*