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

W-fit
Category Name

with model names and reference

Basic UDI-DI: 57138250057Q

Model
W-fit

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

ISO 14971:2019, ISO 13485:2016
Standards

The intended purpose: This product is designed to provide support and comfort for individuals with reduced mobility by reducing pressure points and preventing the development of pressure ulcers. It is intended for use by individuals who sit for extended periods in wheelchairs or other seating devices. The product uses specialized foam to achieve optimal pressure distribution and long-lasting durability, making it suitable for daily 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*