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

Rex

Category Name

with model names and reference

Basic UDI-DI: 571382502782

Model
Rex 350

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, ISO 7176-19:2008

Standards

The intended purpose: Rex 350 is an electric wheelchair designed to enhance mobility for individuals with movement impairments. It is intended for both indoor and outdoor use and is available in sizes suitable for both children and adults. The wheelchair is engineered to support safe and comfortable transportation, featuring a stable and compact frame, a small turning radius for improved maneuverability, and a low seat height for easier access under tables. Rex 350 can be adapted to individual user needs with up to five powered seat adjustments, including elevating leg supports, adjustable backrest angle, seat lift, and seat tilt.

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*