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 - Cushion Cover

Category Name

with model names and reference

Basic UDI-DI: 57138250067S

Model
3D mesh cover

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 10993-5:2009, EN 1021-1:2014, EN 1021-2:2014

Standards

The intended purpose: This cushion cover is an accessory to a pressure-relieving cushion and is intended to protect the cushion from moisture and contamination, as well as to help maintain its pressure-distributing properties. The cover supports the medical function by ensuring hygiene, extending the cushion's lifespan, and contributing to the prevention of pressure ulcers.

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*