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 – Incontinence Cushion Cover

Category Name

with model names and reference

Basic UDI-DI: 57138250307P

Model
Incontinence Smooth side out
Incontinence fabric side out

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, ISO 10993-10:2014

Standards

The intended purpose: This incontinence cover is an accessory to a pressure-relieving cushion and is intended to protect the cushion from moisture and contamination. The cover supports the medical function by ensuring hygiene, preserving the cushion's pressure-distributing properties, and extending its lifespan. It thereby contributes 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*