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

3D Ergo
Category Name

with model names and reference

Basic UDI-DI: 57138250047N

Model
3D Ergo

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 10993-10:2021, ISO 10993-23:2021, EN 1021-2:2014
Standards

The intended purpose: The 3D-printed cushion is designed to enhance pressure distribution, support, and comfort for individuals requiring prolonged sitting assistance. It is specifically engineered to reduce the risk of pressure ulcers by evenly distributing body weight over a larger surface area, thereby minimizing strain on vulnerable regions. Its anatomical design ensures an optimal balance between support and relief, promoting a stable and ergonomically correct sitting posture. The choice of materials and the 3D-printed structure allow for improved ventilation, effectively reducing heat buildup. This product is intended for use in wheelchairs and other seating systems.

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*