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 - XXXXXX**

Name and Address of Manufacturer – Single Registration Number (SRN)

hereby, under our sole responsibility declare, that the product

Manual Wheelchair

Category Name

with model names and reference

Model	Basic UDI-DI	UDI-DI
W5	57138250017G	5713825570546
W5 A	57138250017G	5713825571338
W5 S	57138250017G	5713825570584
W5 K	57138250017G	5713825570577
W5 SL	57138250017G	5713825570591
W5 D	57138250017G	5713825570553
W5 XXL	57138250017G	5713825570607
W5 Junior	57138250017G	5713825570560

is in conformity with the Medical Device Regulation (MDR) 2017/745 as class I medical devices based on Annex VIII and the following standards

DS/EN 12183:2014, DS/EN ISO 14971:2019, ISO 7176-19:2008

Standard(s)

The intended purpose: The manual wheelchair is intended to provide mobility to persons who are unable to walk or who have a mobility problem. It is designed for individual use, and it can be operated either by the patient or by another person. The manual wheelchair can be used both indoors and outdoors.
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

February 11, 2021 - Nibe	Peter Libak, CEO	
Date and place of issue	*Name and position of authorized person*	*Signature of authorized person*