

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 |
|--------------|--------------|---------------|
| Dalton | 57138250017G | 5713825568406 |
| Dalton Low | 57138250017G | 5713825568437 |
| Dalton F | 57138250017G | 5713825568413 |
| Dalton Light | 57138250017G | 5713825568420 |

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 ISO 14971:2019

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

*Date and
place of issue*

Peter Libak, CEO

*Name and position of
authorized person*



*Signature of
authorized person*