

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

Hawk

Category Name

with model names and reference

Basic UDI-DI: 57138250117K

Model
Hawk

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

DS/EN ISO 14971:2019, ISO 13485:2016, DS/EN 12183:2022, ISO 7176-19:2008

Standards

The intended purpose: The Hawk 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. Hawk is a robust fixed frame wheelchair designed for active wheelchair users who require an adjustable wheelchair to accommodate their individual needs and 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

March 31, 2025 - Nibe

*Date and
place of issue*

Peter Libak, CEO

*Name and position of
authorized person*



*Signature of
authorized person*