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

Gitano

Category Name

with model names and reference

Basic UDI-DI: 57138250127M

Model
Gitano
Gitano Junior

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

Standards

The intended purpose: The Gitano 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 three-wheeled design of the Gitano wheelchair provides a significantly smaller turning radius, making it highly maneuverable in tight spaces while ensuring smooth navigation over uneven terrain. Gitano 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	Peter Libak, CEO	
Date and place of issue	*Name and position of authorized person*	*Signature of authorized person*