

EC Declaration of Conformity

Version 4 Date: 04/07/2024

This is to certify that following Medical Devices:

Product	Product code	Basic UDI-DI	Intended purpose
WHEELEO	wheeleo-v2	5430002368WheeleoAX	One-handed rollator intended to aid mobility for people with walking difficulties

are manufactured and sold by

InnoRehab Avenue des Combattants 93 A, 1340 Ottignies Belgium

Single Registration Number: BE-MF-000010049

These products:

- 1. Are classified as Class I devices per Rule 1 of Annex VIII of the Medical Device Regulation 2017/745 as amended.
- 2. Are in conformity with the Medical Device Regulation 2017/745 as amended.
- 3. Comply with the relevant general safety and performance requirements set out in Annex I of the Medical Device Regulation 2017/745 as amended.

This compliance has been properly documented using a checklist created from Annex I of the European Medical Device Regulation, linked to all supporting Technical Documentation set out in Annexes II and III of this Regulation. This documentation included both product specific and process (Quality System) specific documents.

This Declaration is issued under the sole responsibility of InnoRehab.

This Declaration is issued by InnoRehab and has unlimited time validity.

This Declaration is signed below, certifying these requirements have been met and documented.

For InnoRehab, made in Ottignies - Belgium the 04th of July 2024

Geoffroy DELLICOUR

InnoRehab SRL Co-Owner

Gregory VANDERVEKEN

InnoRehab SRL Co-Owner

Reference : F-DND-08 MDR Declaration of Conformity (Template V2 – Edition 06/01/2022)

Archivage : \02-DND\(Project)\07-TCF\20-DoC\R-DND-08 MDR DoC (Project)-YYYYMMDD + Scan;