

EC Declaration of Conformity

Version 1 Date : 25/04/2018

This is to certify that following Medical Devices:

WHEELEO (Product code wheeleo-quad-steel)

are manufactured and sold by

InnoRehab Avenue des Combattants 93 A, 1340 Ottignies Belgium

These products:

- 1. Belong to the Class I according to Rule 1 per Annex II of the European Medical Device Directive (93/42/EEC and its amendments).
- 2. Comply with all Essential Requirements (Annex I) of the European Medical Device Directive.
- 3. Are CE marked in accordance with Annex II of the European Medical Devices Directive.
- 4. This compliance has been properly documented using a checklist created from Annex I of the European Medical Device Directive, linked to all supporting Technical Documentation. This documentation included both product specific and process (Quality System) specific documents.
- 5. Are manufactured in facilities having a Quality System in place.
- 6. This Declaration is issued by INNOREHAB and has unlimited time validity.
- 7. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

For INNOREHAB, made in Ottignies - Belgium the 25th of April 2018

Millicon

Geoffroy DELLICOUR

Owner

Reference: F-DND-08 Declaration of Conformity
Archivage: \02-DND\(Product name)\07-TCF\20