

	CoMoveIT Smart EN Declaration of Conformity	Version : 1.2
	R-DND-08 MDR Declaration of Conformity	Date : 2022-09-22

This is to certify that the following Medical Devices:

Product name	Product code	Basic UDI-DI	Intended purpose
CoMoveIT Smart (family)	CoMoveIT Smart	5430002911CMSMART1DX	Specialty input head/foot steering device for powered wheelchairs

are manufactured and sold by

CoMoveIT NV
Baron Ruzettelaan 5 / 1.1
8310, Assebroek (Bruges)
Belgium

Single Registration Number: BE-MF-000017867

These products:

1. Are classified as Class I devices per Rules 1 and 13 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.
4. Are manufactured in facilities having a Quality System in place based on EN ISO 13485:2016.

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 CoMoveIT NV.

This Declaration is issued by CoMoveIT NV and has unlimited time validity.

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

For CoMoveIT NV, made in Bruges, Belgium
September 22nd, 2022



Mr. Frederik Vervenne
CEO CoMoveIT NV

