CE Declaration of Conformity

Manufacturer:
Hankamp Rehab BV, Buurserstraat 198-200, 7544 RG Enschede; The Netherlands
SRN | NL-MF-000006108

In accordance with the following Regulation:

EU 2017/745 — European Medical Device Regulation
And its amending regulation

Hereby declare under sole responsibility that:

Equipment:	Mbrace Shoulder Support
Classification:	Class I (In accordance with Annex VIII, 2017/745)
Intended Purpose:	Mbrace Shoulder Support relieves and supports the shoulder without restricting functional arm movements

Variations (UDI-DI):		
	Mbrace Shoulder Support - Left Small	(8 720299 662476)
	Mbrace Shoulder Support - Right Small	(8 720299 662483)
	Mbrace Shoulder Support - Left Medium	(8 720299 662490)
	Mbrace Shoulder Support - Right Medium	(8 720892 136404)
	Mbrace Shoulder Support - Left Large	(8 720892 136411)
	Mbrace Shoulder Support - Right Large	(8 720892 136428)
	Mbrace Shoulder Support - Demo kit	(8 720892 136435)

Is in conformity with applicable requirements of the following standards:

Ref. No.	Title	Edition
EN-ISO 20417	Medical devices — Information to be supplied by the manufacturer	2021
EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied - Part 1 – General Requirements	2021
EN ISO 14971	Medical Devices – Application of risk management to medical devices	2019

And is in conformity with the following Common Specifications: -

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above reference specifications. The unit complies with all applicable Essential Requirements of the Regulation.

Signed (date): 18-03-2024

Name: Frederik Tönis, CEO
Place of Issuance: Hankamp Rehab BV, Enschede, the Netherlands
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Conformity assessment procedure: Annex IV of EU 2017/745 considering the amendment by the regulation: EU 2020/561