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:

System name: ReStep fall prevention system

consists of (one or more of) the following CE-marked medical devices:

Device name	Manufacturer	Classification	Variant	UDI-DI
ReStep	Hankamp Rehab	Class I		8 72089 2136442
ReStep Trolley	Hankamp Rehab	Class I		8 72089 2136459
ReStep Harness	Hankamp Rehab	Class I	Small	8 72089 2136480
			Medium	8 72089 2136466
			Large	8 72089 2136473

We confirm that:

- Each device included in this system is CE-marked and used as intended by its original manufacturer.
- The combination of these devices has been assessed to ensure safety, compatibility, and performance in accordance with the manufacturer's instructions.
- The system does not alter the intended purpose of any included device.
- Risk management has been performed in compliance with ISO 14971.
- The system meets the general safety and performance requirements outlined in Annex I of the MDR.
- Proper verification and validation have been conducted to ensure that the system functions as intended.

The system is in conformity with applicable requirements of the following standards:

Ref. No.	Title	Edition
NEN-EN-ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	2016
EN ISO 14971	Medical Devices – Application of risk management to medical devices	2019

Signed (date): 01-05-2026.

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