

## DECLARATION OF CONFORMITY

Name and address of the firm

**Hocoma AG**  
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8604 Volketswil  
Switzerland  
SRN: CH-MF-000014672

EU Authorized Representative

Emergo Europe B.V.  
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The Netherlands  
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Email: EmergoVigilance@ul.com  
SRN: NL-AR-000000116

We declare under our sole responsibility that  
the medical device

**Andago V2.0**  
Basic UDI-DI: 764017466ANUM

Intended purpose

Andago is a therapeutic tool that allows physical therapists and other clinicians to safely perform overground gait and balance training in patients with walking or balance impairments. The Andago provides a dynamic and individually adjustable body weight support system that allows for proper lateral weight shifting, supports the body weight against gravity, and protects from falling to the ground while standing and walking. Andago can be used to support different overground gait training modalities including walking in a straight line, walking following a freely selected path (self-initiated walking) and therapist-controlled walking, following a path controlled by the clinician in charge of the training. Andago facilitates overground gait and balance training by relieving clinicians from having to physically support the patient's body weight and posture. It is always to be used under the supervision of a qualified clinician, who has read and understood the user manual of the Andago. Foreseen settings of application are rehabilitation hospitals, outpatient rehabilitation clinics and other health-care settings, where the device is to be used in spaces suitable for physical therapy and motion exercise, Andago is to be operated in a space with a flat walking surface with adequate no-slip properties, as is common in such facilities.

of class

**Ila**  
according to rule 9 of annex VIII of regulation (EU) 2017/745

meets all the provisions of the Regulation (EU) MDR 2017/745, the Directive on machinery 2006/42/EC and the Directive 2011/65/EU (RoHS), which apply to it.

Conformity assessment procedure

**Annex IX of regulation (EU) 2017/745**  
**Annex VIII of 2006/42/EC**

Common Specifications

N/A

Notified Body (for regulation (EU) 2017/745)

**DEKRA Certification GmbH (0124)**  
**Handwerkstrasse 15**  
**70565 Stuttgart**  
**Germany**


EC Certificate:

**50682-60-00** (expiry date: 24.09.2027)

Volketswil, 30.01.2023



**Silas Passerini**  
**Head of Regulatory Affairs /**  
**PRRC**



**Bernd Henningsen**  
**Chief Specialist Regulatory**  
**Affairs / PRRC**

Place, date

Name and function

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according to Article 15 [3] of regulation (EU)  
2017/745

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