

## **DECLARATION OF CONFORMITY**

Name and address of the firm Hocoma AG

Industriestrasse 4 8604 Volketswil Switzerland

SRN: CH-MF-000014672

EU Authorized Representative Emergo Europe B.V.

Prinsessegracht 20 2514 AP The Hague The Netherlands

Tel: (+31) (0)70 345-8570 Email: EmergoEurope@ul.com SRN: NL-AR-000000116

We declare under our sole responsibility that

the medical device Armeo®Power

Basic UDI-DI: 764017466APUR

Intended purpose The ArmeoPower is a robotic device intended for the

rehabilitation of patients with severe to moderate impairments in upper limb function. The ArmeoPower provides functional training to improve upper limb

function.

of class IIa

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, the Directive 2011/65/EU (RoHS), the Directive 2014/53/EU (RED), which apply to it.

Conformity assessment procedure Annex IX of regulation (EU) 2017/745

Annex VIII of 2006/42/EC Annex II of 2014/53/EU

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

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

2017/745

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