

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
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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 devices

ErigoPro
ErigoBasic
Basic UDI-DI: 764017466ERV9

Intended purpose

The Erigo is a robotic device intended to provide safe verticalization and early functional mobilization of the lower extremity in patients with very reduced or no ambulation ability and/or reduced transfer and standing abilities, who are immobile in bed or in need of a wheelchair for mobility.

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

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