

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 devices

LokomatPro 6.3
Basic UDI-DI: 764017466L6U8
LokomatNanos 1.3
Basic UDI-DI: 764017466LNVN

Intended purpose

The Lokomat is a robotic device intended to enable intensive rehabilitative gait therapy in adult and pediatric patients with severe to moderate impairments in walking abilities and functional 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), 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

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