

mobility media medical

Head office: Žitná 570/26 120 00, Praha 2 - Vinohrady Czech republic, Europe VAT ID: CZ29051886 phone: +420 732 182 173 email: info@volter.cz

# **DECLARATION OF CONFORMITY**

(in accordance with the requirements of the Council of Europe 2017/745 EEC, Law no. 2020/561 Coll., on medical devices and government regulation no. 89/2021 Coll., establishing technical requirements for medical devices)

# Manufacturer:

Volter s.r.o Žitná 570/26 Prague 2 – Vinohrady CZ-120 00

#### Seat of manufacturer:

Volter s.r.o Žitná 570/26 Prague 2 – Vinohrady CZ-120 00

Product: medical stroller xRover

Model marking: "XROVER REHA M" "XROVER REHA L"

## **Claassification:**

according to European Council Directive 2017/745 EEC non-invasive medical device Class I

## **EC certificates:**

- in accordance with the requirements of the Council of Europe 2017/745 EEC, Law no. 2020/561 Coll., on medical devices and government regulation no. 89/2021 Coll., establishing technical requirements for medical devices
- in accordance with final protocol (Nr. of certificate: 32-0329), provided by Certify EU Testing Authority (Strojírenský zkušební ústav, Czech Republic) and in fully accordance with applicable requirements of EN 12182:2012 (Assistive products for persons with disability. General requirements and test methods) and of EN ISO/IEC 17067:2014.

We hereby declare that the foregoing medical device with trade name "xRover REHA M a xRover REHA L" – medical stroller meet all the relevant provisions of the Council of Europe 2017/745 EEC, Law no. 2020/561 Coll., on medical devices and government regulation no. 89/2021 Coll. And establishing technical requirements for medical devices.





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All the background information is under the control of the manufacturer.

## Signatures, date of issue:

Name: Petr Mudra

Function: business and executive director

Signature:

date of issue: 03 June 2021

Name: Jiri Vavra

Function: executive director

date of issue: 03 June 2021 Signature:

