

DECLARATION OF CONFORMITY

(in accordance with the requirements of the Council of Europe 93/42 / EEC, Law no. 268/2014 Coll., on medical devices and government regulation no. 54/2015 Coll., establishing technical requirements for medical devices)

Legal Manufacturer:

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

Seat of Legal Manufacturer:

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

Product Name: Medical Stroller xRover

Model marking:

„xRover REHA M“
„xRover REHA L“

Classification:

according to European Council Directive 93/42 / EEC non-invasive medical device Class I

EC certificates:

- in accordance with the requirements of the Council of Europe 93/42 / EEC, Law no. 268/2014 Coll., on medical devices and government regulation no. 54/2015 Coll., establishing technical requirements for medical devices
- in accordance with final protocol (Nr. of certificate: 32-0329), dated on 15th Sep 2017 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 devices with trade name "xRover REHA M a xRover REHA L" – medical stroller meet all the relevant provisions of the Council of Europe 93/42/EEC, Law no. 268/2014 Coll., On medical devices and amending related laws, as amended by subsequent legislation, and government regulation no. 54/2015 Coll., establishing technical requirements for medical devices

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



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mobility media medical

Signatures, date of issue:

Name: Petr Mudra

Function: executive director

Signature:

A handwritten signature in blue ink, appearing to read 'P. Mudra', on a light blue rectangular background.

date of issue: 1.12.2017

