

# ExoAtlet

Exoskeletons for medical rehabilitation

04.02.2021

Legal aspects  
of working with  
ExoAtlet.

EXOATLET



# Certificates

- ✓ Notified Body Certificate (CE Mark)
- ✓ ISO
- ✓ EC DECLARATION OF CONFORMITY
- ✓ USER MANUAL

Currently there is no open central database in EU for CE certificates and medical devices.

To validate that the certificate, provided in the documentation is correct, you should contact the notified body that issued the certificate.

**EUDAMED** – new module on Certificates and Notified Bodies will become available by May 2021.

Eudamed2 is a secure, web-based portal for information exchanged between national competent authorities and the Commission and is not publicly accessible.

ExoAtlet-II  
ExoAtlet-II User Manual

**WE  
RAISE  
YOU  
UP!**

EXOATLET | CE | KC

**MTIC**  
INTERCERT  
CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE  
n. 0068/QPZ-DM/206-2020  
according to Annex V of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned firm production quality system has been carried out following the requirements of the legislation to which the under signed is subjected, transposing annex V of the directive 93/42/EEC on Medical Devices. MTIC Intercert certifies that the production quality system conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

**MANUFACTURER:** ExoAtlet Asia Co., Ltd.  
5F, Happyland, 66, Digital-ro 31 gil, Guro-gu, Seoul (REP. OF KOREA)

**DEVICE:** Powered lower extremity exoskeleton

**MODEL:** ExoAtlet®-II

DATE OF ISSUE: 18/04/2020 | CURRENT ISSUE: 18/06/2020 | SURVEILLANCE NO: 00 | EXPIRES DATE: 27/05/2024

MTIC Intercert S.p.A. - Via Cassanese 11 - 20139 Sesto San Giovanni (MI) - Italy  
Tel: +39 02 77071800 | Fax: +39 02 9308175  
Website: www.mticert.org

EXOATLETASIA Co., Ltd. Declaration of conformity May 21, 2020/DOC-06/03

**EC DECLARATION OF CONFORMITY**

The above designated product is in conformity with the European Directives

**MANUFACTURER:** EXOATLETASIA Co., Ltd.  
5F, Happyland, 66, Digital-ro 31 gil, Guro-gu, Seoul, Korea

**PRODUCT:** Powered Lower Extremity Exoskeleton  
**Model / Type Ref.:** ExoAtlet® II / EA5010

WE HAVE BEEN DECLARED THAT TO CONFORM TO THE SAFETY AND HEALTH CONDITIONS ACCORDING TO 2006/42/EC MACHINERY DIRECTIVE. It is confirmed that a sample of the product has been tested and found in conformity with below standard(s):

**EN ISO 12100:2010**

**NOTIFIED BODY NAME AND ADDRESS AND NOTIFIED BODY NUMBER:**  
- Notified Body name and number: MTIC Intercert S.r.l. CE 0068  
- Notified Body address: Via Moscova 11 20017 9101 Milano, ITALY  
- Contact:  
Phone: +39 02 97071800 Fax: +39 02 9308175  
Website: www.mticert.org

**APPLIED DIRECTIVES:** 2006/42/EC Machinery Equipment Directive

**EU REPRESENTATIVE:**  
- EU Representative: ExoAtlet Global S.A.  
- EU Representative address: 70 route d'Esch, L-1470 Luxembourg  
- Contact: Tel) +31624147046

**CE**  
0068  
Date: Feb. 18, 2020  
Signature: *Oh Joo Young*  
EXOATLETASIA Co., Ltd.  
President Oh Joo Young

EXOATLETASIA Co., Ltd. A42100297/rev

EXOATLETASIA Co., Ltd. Declaration of conformity May 21, 2020/DOC-06/03

**DoC Declaration of Conformity** **RoHS**

The above designated product is in conformity with the European Directives

**2011/65/EU, including amendments**

**MANUFACTURER:** EXOATLETASIA Co., Ltd.  
5F, Happyland, 66, Digital-ro 31 gil, Guro-gu, Seoul, Korea

**PRODUCT:** Powered Lower Extremity Exoskeleton  
**Model / Type Ref.:** ExoAtlet® II / EA5010

This EC Declaration of conformity is following the provisions of RoHS DIRECTIVE 2011/65/EU. It is confirmed that a sample of the product has been tested and found in conformity with below standard(s):

**RoHS EN 50581 : 2012  
IEC 62321 : 2008**

IDENTIFICATION OF THE SIGNATORY WHO HAS BEEN EMPOWERED TO ENTER INTO COMMITMENTS ON BEHALF OF THE MANUFACTURE AND AUTHORIZED REPRESENTATIVE ESTABLISHED WITHIN THE COMMUNITY.

Date of issue: Feb. 18, 2020  
Authorized By: *Oh Joo Young*  
President

EXOATLETASIA Co., Ltd.  
5F, Happyland, 66, Digital-ro 31 gil, Guro-gu, Seoul, Korea

EXOATLETASIA Co., Ltd. A42100297/rev

# Sales to Individuals

- Allowed for the ExoAtlet II (CE mark)
- Accordance to the user manual:
  - User recommendations
  - Consultation with physician
  - Passing medical exams and checks
- Specifics of the contract with Individuals
- Price for individuals includes VAT of the Country

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## User's Physical Condition

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### User Recommendations

- Exoskeleton users should consult with a physician prior to training in the system.
- 18 years of age or older (Wearers of the device are recommended to use after professional consultation)
- Height between 150-190 cm (Recommended to use after professional consultation regarding height)
- Weight less than 100 kg (Recommended to use after professional consultation if the user is obese or has a BMI of 25 or more)

### User Restrictions

- User is pregnant
- Unable to communicate due to cognitive or language disorders
- Contractions in the hip or knee joints.
- Severe muscle stiffness in the lower extremities (MAS Grade 3 or higher)
- Bone osteoporosis or low bone density (BMD ( $t \geq -3.5$ ))
- Fractures or incomplete bone junctions in the spine, pelvis and lower extremities
- Severe arthritis, acute arthritis, or synovitis after total or partial joint surgery
- Skin disease on the buttocks, lower limb joints and areas where robot straps are worn
- Orthostatic hypotension, essential hypertension or uncontrolled blood pressure
- Myocardial infarction, angina, or ischemic heart disease within the last 6 months
- Unmodulated heart functions, such as tachycardia, bradycardia, or arrhythmia
- Unmodulated diabetes
- Presence of infections or other serious complications

\*In the event of an illness or condition other than the above conditions, consult with a professional before determining whether the product is right for you.



If an accident occurs due to usage without professional consultation, the user may be held liable. Please **consult with a professional** before use.