

**“ZEUS the bionic limb
– Terms and Conditions”
binding as of 1st June 2022**

1. GENERAL INFORMATION

1.1. Introduction

This document sets forth the terms and conditions for the use of Zeus and contains information on:

- (a) Zeus intended use,
- (b) support and training,
- (c) maintenance and servicing,
- (d) warranty terms,
- (e) regulatory compliance and certification,
- (f) manufacturer’s liability.

1.2. About Company

Aether Biomedical sp. z o.o. – a **manufacturer of Zeus the bionic limb** – is a medical robotics company focused on biosignal processing and bionic limbs for upper limb amputees.

1.3. Product Description

Zeus is a **multi-action bionic limb** combining ease of control with elegant, robust design.

2. DEFINITIONS

Unless otherwise expressly provided to the contrary in these Terms and Conditions, all capitalized terms used herein shall have their respective meanings set forth below:

Aether or we means Aether Biomedical sp. z o.o. (*polish limited liability company*) with its registered office in Poznan, address: ul. Krolowej Jadwigi 43, 61-871 Poznan, entered into the register of entrepreneurs of the National Court Register Poznan – Nowe Miasto i Wilda, VIII Commercial Division of the National Court Register under KRS No.: 0000755184, REGON: 381661137, NIP: 7831791083.

Consumer means an individual who purchases the Product for personal use.

Maintenance means the process during which all Product functions are extensively tested, the worn mechanical parts are replaced,

Medical Center

the required firmware updates and technical updates are performed. **“Maintenance”** also includes cleaning.

means a medical prosthetic and orthotic center providing medical services to the Patients, authorized by Aether to resale the Product and provide training to the Patients with respect to the Product. **“Medical Centers”** are solely responsible for the assembly and installation of the Product to the Patients, including but not limited to calibration of the Product, positioning of electrodes and sensors, setup of the Product using the Software, and for the design and fabrication of the prosthetic socket. **“Medical Centers”** are the first point of contact for the Users.

Product

means the whole arm prosthesis system combined of: (i) (i) a multi action bionic limb available in left hand (A-01-L) or right hand (A-01-R) configuration, (ii) instruction for use (0704_IFU), (iii) user guide (U01DC-0100), (iv) software instruction (U01DC-0400), (v) Quick start guide for clinicians (U01DC-0200), (vi) accessories kit (AC-01), (vii) Zeus configurator web application v 1.00 or higher, (viii) the prosthetic socket fabricated by Medical Centers.

Qualified Personnel

mean the clinical team of certified/licensed professionals who provide medical or healthcare services to the Patients at the Medical Centers, consisting of certified prosthetists and/or orthotists, prosthetic assistants, technicians and other practitioners.

Repair

means the process during which Aether’s qualified service technicians or technical

partners analyze the Product and perform a mechanical-functional test. Affected parts or components are assessed and replaced or repaired according to Aether’s servicing directives. In addition, service inspections as well as cleaning are carried out. Zeus’ **“Repairs”** within the scope of Warranty are free of charge during Warranty Period. After Warranty Period, **“Repairs”** are charged based on a cost estimate on request.

Software means an interface software licensed by Aether to the Medical Centers for Zeus configuration. The **“Software”** is designed for use only by Qualified Personnel to for installation, calibration and servicing of the Product.

Terms and Conditions means these terms and conditions.

User Manual means the document containing important information on the correct use and care of Zeus which shall be provided to the Patient in paper form along with the Product. Aether may update or modify the **“User Manual”** from time to time.

User, Patient or you means an individual receiving or having received preventive, diagnostic, therapeutic, rehabilitative, or maintenance health services from the Medical Center, who purchased the Product.

Warranty shall have the meaning set out in clause 6.1.

Warranty Period shall have the meaning set out in clause 6.3.

Zeus means a multi-action bionic limb available in left hand (A-01-L) or right hand (A-01-R) configuration, manufactured by Aether.

3. INTENDED USE

3.1. Zeus is an external limb prosthetic component intended to be used with other compatible system components (including electrodes, battery systems, connector “Quick Disconnect Wrist” and cables) by Qualified Personnel to provide Patient a complete arm prosthesis system (Product).

3.2. Zeus is designed to be used only by Patients with upper limb loss or deficiency and by Patients with congenital absence of an upper limb (forearm). The final decision whether Zeus is suitable for the Patient belongs to the Qualified Personnel. Qualifications and fitting of the Product to the Patient’s upper limb may be exclusively done by the Qualified Personnel of the authorized Medical Centers.

3.3. Zeus is designed for use only on one Patient during the whole service life of the prosthesis. Depending on the Patient’s activity the estimated service life of Zeus is up to 5 (five) years. The service life can be individually extended depending on the intensity of use and by performing regular Maintenance inspections as set out in clause 5.5.

3.4. Zeus is designed for mild to moderate activities. Its functionality covers most of the hand movements. Please avoid use in situations with heavy loads, vibrations or impacts. **For more detailed information on the intended use of the Product please refer to the User Manual.**

3.5. You shall use the Product in accordance with the User Manual, guidelines provided during training and in conjunction with advice from your Qualified Personnel. Please read the User Manual thoroughly before using Zeus. Please refer to www.aetherbiomedical.com to ensure you are viewing the latest version of the User Manual and relevant Product information.

3.6. Please be aware that the Product comes with the Software which is not intended for Patient use. Alterations should be made by the Qualified Personnel only.

3.7. If you have any specific questions about your Product, please contact your Qualified Personnel or visit the Aether website www.aetherbiomedical.com for the latest information and news.

4. SUPPORT AND TRAINING

4.1. The Patient must be taught how to handle, care for and operate his/her Zeus properly. The User Manual along with the training and support provided by the Qualified Personnel of the Medical Center should help the Patient understand how

- Zeus will help him/her to accomplish their functional goals.
- 4.2. Patient shall be trained with Zeus by the Qualified Personnel from the Medical Center which has sold and fitted Zeus to the Patient.
 - 4.3. The Qualified Personnel will assist you to become proficient in using your Zeus. The term and scope of training varies depending on given Patient's condition, activity etc. and shall be each determined by Qualified Personnel. During the training sessions different aspects of your everyday activities will be explored. You can get the most from training by listing and suggesting those tasks that you want to achieve. Also, you shall have discussed your functional goals with your Qualified Personnel. You can then work through this list with your team of Qualified Personnel. To get the most from the Zeus, make sure your arm is comfortable, secure and functional.
 - 4.4. To learn about the list of current Aether's Medical Centers - contact Aether via the contact form available on www.aetherbiomedical.com.
- 5. MAINTENANCE AND SERVICING**
- 5.1 Maintenance, Repairs and servicing of the Product may only be performed by qualified Aether's technicians and technical partners. Contact your local Medical Center for all service related concerns.
 - 5.2 You should inspect your Product regularly to identify potential problems early. If the Product doesn't function as you think it should, contact the Medical Center where you purchased the Product which will be able to provide you guidance.
 - 5.3 If you experience any technical problems with the Product and your Qualified Personnel is not available, contact Aether via the contact form available on www.aetherbiomedical.com.
 - 5.4 We strongly recommend that you do not adjust, dismantle, attempt to maintain or modify your Product. Moreover, never attempt to open, disassemble, modify, or repair any component of the Product, including accessories.
 - 5.5 To ensure Patient's safety, proper performance of the Product and in order to maintain operating safety and protect the Warranty, regular Maintenance of Zeus must be carried out, i.e. every 6 (six) months from the date of purchase. Your Qualified Personnel shall provide you with the next Maintenance date.
- 5.6 Zeus is eligible for one free Maintenance every 6 months during the Warranty Period as set out in clause 6.3. After Warranty Period, Maintenance is charged based on a cost estimate on request.
 - 5.7 Medical Center shall notify you on the obligatory Maintenance – each every 6 (six) months.
 - 5.8 Aether shall not liable for any malfunction of Zeus if it is the result or is related to incorrect or untimely perform of Medical Center's or Patient's obligations with respect to Maintenance.
 - 5.9 If Zeus is to be returned for Maintenance or servicing, please contact your Medical Center stating the Zeus hand's serial number. The serial number can be found on the part called "Quick Disconnect Wrist". We will issue a returns form that shall be completed in full so your request can be dealt with promptly.
- 6. WARRANTY TERMS**
- 6.1. **Limited Warranty**
Aether warrants to the User (original purchaser of the Product from Medical Center) that Zeus is free from defects in materials and workmanship. This Warranty applies, subject to normal wear and tear, when Zeus is used as intended, without unapproved modifications, following all Aether instructions and requirements, in particular in accordance with the User Manual; and when Zeus is fitted by the Qualified Personnel who meet all Aether product-specific training requirements as needed for Zeus.
 - 6.2. **Exclusion of Warranty**
This warranty does not apply if Zeus (1) was not purchased from Aether or its authorized Medical Center, (2) has been altered or modified in any way, subject to any modifications performed by Qualified Personnel which are accepted by Aether, (3) has not been used in accordance with the User Manual, (4) has not been maintained as set out in clause 5.5, or (5) has been repaired or maintained by an uncertified person, or (6) has been programmed or controlled with unapproved, alternative software or by unauthorized person. This Warranty does not cover damage due to accidents, neglect, misuse, abuse, or operation beyond capacity, parts damaged by improper installation, substitution of parts not approved by Aether, or any other alteration or repair by others that, in Aether's judgment, materially or adversely affects Zeus or any part thereof.

This Warranty does not apply to the Product's components manufactured by third parties, such as batteries, the electrode system (the relevant

warranty terms of the components' manufacturers are enclosed separately) and the prosthetic socket (manufactured by the Medical Centers).

This Warranty is governed by Polish law and is not transferrable.

6.3. **Warranty Period**

- (a) The Zeus comes with a **2-year-standard manufacturer's Warranty** from Aether. The Warranty is effective from the date of delivery of the Product to the User.
- (b) In addition, the **3-year extension** from 2- to **5-year Warranty** can be purchased at the date of purchase of the Product.

6.4. **Scope of Warranty**

The Warranty includes:

- (a) free of charge Repair of Zeus*;
- (b) free of charge replacement unit for the period of Repair and Maintenance during the Warranty Period.

* Repairs do not cover superficial damage, such as scratches indicating signs of use.

6.5. **Reporting Warranty claims and returning Products**

To obtain the benefits of this Warranty, any suspected defect must both be reported to the Medical Center and the affected Product must be delivered to Medical Center where you purchased the Product within 7 (seven) days of the defect having occurred within the Warranty Period. When returning a Product for any reasons specified in this Warranty, the entire Product must be returned in the original packaging to ensure safe transport.

Where a claim is made under Warranty, this claim must be supported by appropriate documentation.

In the event you do not receive satisfactory Warranty service, contact Aether contact Aether via the contact form available on www.aetherbiomedical.com. Provide the name of Medical Center from which you purchased your Product, copy of commercial invoice on purchasing Zeus, address, date of purchase, indicate nature of the defect and the Zeus' serial number. Do not return any Products to Aether's location without prior consent.

6.6. **Components**

The manufacturers of the Product components, such as the battery and the electrode system

provide their own warranty terms, as attached hereto as Schedules.

Upon prior consent of Aether, Medical Centers may decide to use other Product's components than the ones provided by Aether (inter alia: battery, electrodes system). Before of any use of such components, Patient shall receive form Medical Center the warranty terms for such alternative components implemented by the Medical Centers.

6.7. **Warranty disclaimer**

THE EXPRESS WARRANTY SET FORTH HEREINABOVE IS EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES WHATSOEVER, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ALL SUCH OTHER WARRANTIES ARE HEREBY DISCLAIMED AND EXCLUDED BY AETHER. TO THE MAXIMUM EXTENT PERMITTED BY LAW THE SOLE REMEDY FOR VIOLATIONS OF ANY WARRANTY WHATSOEVER, SHALL BE LIMITED TO REPAIR OF THE DEFECTIVE ZEUS HAND PURSUANT TO THE TERMS CONTAINED HEREIN. IN NO EVENT SHALL AETHER'S LIABILITY OF ANY KIND INCLUDE ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, EVEN IF AETHER SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL LOSS OR DAMAGE.

This Warranty gives the Consumer specific legal rights. The Consumer may also have other legal rights which vary from country to country. Some countries and states may not allow the exclusion or limitation of incidental or consequential damages or warranties, so the above limitations or exclusions may not apply to you. This Warranty shall be extended to comply with state/provincial laws and requirements.

7. **REGULATORY COMPLIANCE AND CERTIFICATES**

7.1 We declare that we meet the appropriate European quality standards for design, manufacture and supply of prosthetic products and user software. Continued compliance with these standards is monitored by a program of internal audits.

7.2 As a manufacturer of medical equipment, we are following the strict requirements of the Medical Devices Regulation 2017/745 (MDR), and the Act of 7 April 2022 on the Medical Device.

7.3 Our Products are entitled for the CE sign and all individual Products are marked indicating that they comply with the requirements of the abovementioned Regulation 2017/745. The "CE" mark may be applied on packaging or accompanying documents, rather than the Product itself.

7.4 Zeus and its associated components listed in this document are covered by test certificates for:

Applicable standards:

- (a) EN 60601-1
- (b) EN 60601-1-2
- (c) EN 60601-1-11
- (d) EN 62366
- (e) EN ISO 14971
- (f) IEC 62304
- (g) EN 1041

Applicable EU Harmonised Regulation:

- (a) Medical Device Regulation 2017/745
- (b) RoHS Directive 2011/65/EU
- (c) WEEE Directive 2012/19/EU

8. LIMITATION OF LIABILITY

- 8.1. Aether is solely liable to the Users for the technical and functional aspects of the Zeus.
- 8.2. Aether explicitly states that Zeus may only be used under the specified conditions and for the intended purpose, and in combination with components provided in the Product kit (as described in the definition of the "Product" set out in section 2) or other components that were authorised by Aether, and in accordance with User Manual. Aether does not assume liability for damage caused by component combinations that were not authorised by Aether. Use of unauthorized components in conjunction with Zeus will void any warranty or other obligation, express or implied, of Aether.
- 8.3. Aether shall not be liable in any way for any damages or injuries caused by improper use of the Product.
- 8.4. Aether disclaims any liability related to medical decisions made by the Qualified Personnel, any failures in the assembly or installation of the Product to the Patient or improper training provided by the Qualified Personnel.

8.5. Some jurisdictions do not allow the limitation or exclusion of liability for certain types of damages. Accordingly, some of the above disclaimers and limitations may not apply to you. To the extent that Aether may not, as a matter of applicable law, disclaim or limit its liability as set forth herein, the extent of Aether's liability shall be the minimum permitted under such applicable law. In particular, nothing in these Terms and Conditions shall affect the statutory rights of any Consumer or exclude or restrict any liability for death or personal injury arising from any negligence or fraud of Aether.

9. FINAL PROVISIONS

9.1. Amendments to the Terms and Conditions

Aether may update or modify these Terms and Conditions from time to time. The current version of Terms and Conditions may be found at: www.aetherbiomedical.com.

9.2. Questions, inquiries or comments

Any questions, inquiries or comments regarding the Product may be sent by e-mail at: info@aetherbiomedical.com.

9.3. Severability

If any portion of these Terms and Conditions is found illegal or unenforceable, in whole or in part by any court of competent jurisdiction, such provision shall, as to such jurisdiction, be ineffective solely to the extent of such determination of invalidity or unenforceability without affecting the validity or enforceability thereof in any other manner or jurisdiction and without affecting the remaining provisions of these Terms and Conditions, which shall continue to be in full force and effect.

9.4. Governing law

To the extent permitted by applicable law, these Terms and Conditions are governed by and construed in accordance with the laws of Poland, without regard to conflict of law provisions. Except where prohibited and without limitation to any statutory rights for Consumers, you agree that the courts of Poland shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with these Terms and Conditions or its subject matter.