

LeoShape SaaS Terms of Service

Service Provision Outside the United States of America: For Subscribers located outside of the United States, the SaaS services shall be provided by Leopoly Ltd., a Hungarian corporation with its registered office at 6000 Kecskemét, Homokszem u. 3., registration number: 03-09-132201. **Service Provision within the United States of America (USA):** For Subscribers located within the United States of America, the SaaS services shall be provided by Leopoly Next Inc., address: 3 E 3RD AVE San Mateo Clocktower, CA 94401, registration number: 5366000, a company incorporated under the laws of the United States of America.

In this agreement, Leopoly Ltd. and Leopoly Next Inc. will be collectively referred to as "**Leopoly**" or "**Service Provider.**"

All terms and conditions of this agreement shall be governed by and construed in accordance with the laws of Hungary, including compliance with relevant data protection regulations such as the General Data Protection Regulation (GDPR). Additionally, for operations and users within the United States, the agreement shall comply with applicable US laws, including the Health Insurance Portability and Accountability Act (HIPAA), the Delaware Personal Data Privacy Act (DPDPA), and other relevant federal or state privacy regulations.

Subscriber and Service Provider shall also be referred to as "Party" or collectively as "Parties".

The Parties hereby agree as follows:

1. DEFINITIONS

1.1 "Affiliate" means, with respect to any Person, any other Person that, directly or indirectly, Controls, is Controlled by, or is under common Control with, such specified Person.

1.2 "Agreement" means this Agreement including all attachments, annexes, schedules, and other additional documents that relate to it.

1.3 "Confidential Information" means technical information, including without limitation the Intellectual Property, as well as information about product plans and strategies, promotions, customers, and related non-technical business information passed to the other Party whether orally or in writing, directly or indirectly.

1.4 "Order Confirmation" means the confirmation of the mutual agreement and unique arrangement between the Parties under these Terms of Service, which includes, among other things, the necessary developments for customization, the agreed Service Level Agreement (SLA), and any specific Subscriber fees.

1.5 "Patient Data" means any personal health data, biometric data, 3D anatomical scans, medical notes, or Protected Health Information (as defined under HIPAA¹) regarding the Subscriber's patients, uploaded or processed through the Service.

1.6 "Software" means the LeoShape software solutions, the Order Management System (OMS), and the LeoCapture (LeoScan) applications, which are built upon the proprietary LeoEngine.

1.7 "Subscriber" means an individual or entity (e.g., a clinic, lab, or medical professional) that has entered into this Agreement with the Service Provider to access and use the Software.

1.8 "User" means an individual authorized by the Subscriber to use the Services (e.g., the Subscriber's employees, clinicians, or technicians).

1.9 "Service" means the cloud-based services provided by Leopoly as a result of the Subscriber's access and use of the Software (LeoShape, OMS, LeoCapture), including all updates and upgrades.

1.10 "BAA" means the Business Associate Agreement (for US Subscribers subject to HIPAA) **and "DPA"** means the Data Processing Agreement (for EU/Global Subscribers subject to GDPR), respectively, which govern the processing of Patient Data and form an integral part of this Agreement.

2. PROPRIETARY RIGHTS AND LICENCES

2.1 Reservation of Rights: Subject to the limited rights expressly granted herein, the Service Provider, its Affiliates, and its licensors own all rights, titles, and interests in and to all copyright, trademark rights, patent rights, design rights, and other IP Rights associated with the Software and Services. Subscriber agrees that all trade names, trademarks, domain names, copyrights, and trade secrets related to the Services shall remain at all times the exclusive property of the Service Provider. **2.2 License to Host Subscriber Data:** The Subscriber grants the Service Provider a worldwide license to host, copy, transmit, and display the Subscriber's Data (including Patient Data) as reasonably necessary for the Service Provider to provide the Services in accordance with this Agreement, the DPA, and the BAA.

3. USE OF SERVICES

3.1 Service Access: Service Provider hereby grants to Subscriber, during the Term, a non-exclusive, worldwide right to access and use the Service for Subscriber's internal business purposes, as specified in the Order Confirmation. **3.2 Usage Limits:** The Services are subject to usage limits, including quantities of edits, downloads, or Users specified in the Order Confirmation. **3.3 Subscriber Responsibilities:** The Subscriber will: (a) be responsible for ensuring that Users comply with this Agreement; (b) **be solely responsible for the accuracy,**

¹ <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html#what>

quality, and legality of the data provided, including the absolute obligation to obtain all legally required consents, waivers, and authorizations from patients prior to capturing, uploading, or processing their personal data, 3D scans, and Protected Health Information within the Services; (c) use commercially reasonable efforts to prevent unauthorized access to the Services; and (d) use the Services only in accordance with this Agreement, the DPA/BAA, and all applicable healthcare and privacy laws.

4. COVENANTS AND RESTRICTIONS

4.1 Restrictions: Subscriber will not disassemble, reverse engineer, or decompile any Service without written authorization from Service Provider. **4.2 Marketing:** Both Parties are committed to sharing positive news regarding their collaboration, provided it does not violate patient confidentiality. Subscriber shall not perform any advertising or marketing activities which may harm Service Provider's reputation or trademark.

5. SERVICE MAINTENANCE AND SUPPORT

5.1 Support: Service Provider shall provide Subscriber with support and ensure service availability in accordance with the current Service Level Agreement (SLA) available at [link], which is incorporated herein by reference. Specific SLAs may be defined or overridden in the individual Order Confirmation.

6. FINANCIAL PROVISIONS

6.1 Fees: The Subscriber is required to pay fees based on the Order Confirmation (e.g., Pay-As-You-Go per download/edit, or prepaid subscription). **6.2 Payment Terms:** All valid invoices will be paid within 8 days unless otherwise agreed. Overdue charges may accrue late interest. **6.3 Suspension of Service:** If any amount owing is 14 days overdue, the Service Provider may suspend the Services until such amounts are paid in full.

7. DATA PRIVACY, SECURITY, AND COMPLIANCE

7.1 HIPAA Compliance (US): If the Subscriber is a "Covered Entity" under HIPAA and utilizes the Services to process Protected Health Information (PHI), the Parties are automatically bound by the Service Provider's standard **Business Associate Agreement (BAA)**, which is incorporated herein by reference. **7.2 GDPR Compliance (EU/Global):** If the Subscriber processes personal data subject to the GDPR, the Parties are automatically bound by the Service Provider's standard **Data Processing Agreement (DPA)**, which is incorporated herein by reference. In this context, the Subscriber acts as the Data Controller, and the Service Provider acts as the Data Processor. **7.3 Data Security:** The Service Provider implements industry-standard technical and organizational security measures, including encryption of data in transit and at rest, to ensure the confidentiality and integrity of Patient Data. **7.4 Privacy Policy:** The processing of User and Subscriber personal data is further described in the Leopold Privacy Policy, available on our platform.

8. WARRANTIES AND MEDICAL DISCLAIMER

8.1 General Warranty: Service Provider warrants that it has full power and authority to grant Subscriber the rights granted herein. **8.2 Service Warranty:** The Service Provider warrants that the Service will operate in accordance with its Specifications and the SLA. **8.3 MEDICAL DISCLAIMER (IMPORTANT):** The Services (including LeoShape, OMS, and LeoCapture) are software tools intended solely to assist medical professionals, clinics, and laboratories in the digital capture, design, and order management of orthotic and prosthetic devices. The Service Provider is a software developer and does not provide medical advice, medical diagnoses, or clinical treatments. The Subscriber (and its authorized clinicians) retains full and exclusive professional responsibility for all medical decisions, clinical evaluations, and the physical safety, efficacy, structural integrity, and clinical suitability of any custom orthosis or prosthesis manufactured using data generated by the Services. **8.4 Warranty Disclaimer:** EXCEPT AS EXPRESSLY PROVIDED HEREIN, SERVICE PROVIDER MAKES NO WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, AND SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE TO THE MAXIMUM EXTENT PERMITTED BY LAW.

9. INDEMNITY

9.1 Subscriber agrees to defend, indemnify and hold harmless Service Provider against any liability, losses, damages, fines, or costs (including legal costs) incurred or suffered by Service Provider as a result of any breach or negligent act by Subscriber. **This explicitly includes indemnification for any claims, regulatory fines, or damages arising from the Subscriber's failure to obtain proper patient consent for data processing under HIPAA, GDPR, or other applicable laws, or arising from medical malpractice claims related to devices designed using the Services.**

10. LIMITATION OF LIABILITY

10.1 Except in the case of direct and willful misconduct, in no event shall the Service Provider's liability arising out of or related to a specific design, editing, or downloading event exceed the total amount of fees actually paid by the Subscriber for that specific design/order under this Agreement.

11. TERM AND TERMINATION

11.1 Term: This Agreement is effective upon the purchase of a Subscription and shall automatically renew unless terminated with a 30-day written notice.

11.2 Termination for Cause: Either party may terminate upon 30 days' written notice of an uncured material breach.

11.3 Data Deletion upon Termination: Upon termination, and subject to the terms of the DPA/BAA, the Service Provider will make the Subscriber's data available for export. After the transition period, the Service Provider will securely delete or destroy all Patient Data and 3D designs from its systems, as required by applicable privacy laws.

12. CONFIDENTIALITY

12.1 The Parties shall treat all business, technical, and pricing information as Confidential Information and shall not disclose it to third parties without prior written consent, except as required by law.

13. MISCELLANEOUS CLAUSES

13.1 Assignment: Neither Party may assign this agreement without the other Party's written consent. **13.2 Force Majeure:** Neither party will be liable for performance delays caused by events beyond their reasonable control. **13.3 Governing Law & Dispute Resolution (Outside US):** For Parties outside the US, this Agreement is governed by the laws of Hungary. Disputes shall be resolved by the Permanent Arbitral Tribunal at the Hungarian Chamber of Commerce and Industry in Budapest. **13.4 Governing Law & Dispute Resolution (Inside US):** For Parties in the US, this Agreement is governed by Delaware law. Disputes shall be resolved through arbitration under the Delaware Rapid Arbitration Act (DRAA). **13.5 Entire Agreement:** This Agreement, together with the Order Confirmation, SLA, DPA, and BAA, constitutes the entire agreement between the Parties.

By accessing or using the Software and Services of Leopoly, the Subscriber acknowledges that they have read, understood, and agree to be bound by these Terms of Service.