

PREDISURGE GENERAL CONDITIONS OF USE AND SALES (GCUS)

PrediSurge, a Simplified Joint Stock Company (Société par actions simplifiée) registered at the RCS of Saint-Etienne under the number 829 714 203, whose registered office is located at 2 Parvis Pierre Laroque - Immeuble One Station - 42000 Saint-Etienne-France (hereinafter "**PrediSurge**").

Applicable start date: July 23rd, 2026

1 Acceptance and Scope of the Agreement

- 1.1 Scope of Offerings. These GCUS and their annexes govern the provision and use of PrediSurge's software, hosted solutions, and related services (collectively, the "Offerings"), whether free or paid, including but not limited to:
 - a. Numerical simulations outputs (3D models, report files) (the "Simulation").
 - b. Automatic sizing results including DICOM Viewer usage and report files (the "Sizing").
 - c. The access right to the electronic platform located at www.planop.ai (the "Platform"), including PlanOp® Platform and PlanOp® iSizing products.
 - d. Any associated support or advisory services ("Support").
- 1.2 **Acceptance.** Access to and use of the Offerings are subject to these GCUS. These GCUS and their annexes are accepted by the Client and, where applicable, by each individual accessing or using the Offerings (the "**Authorized User**"). Where the Client is an individual acting in a professional capacity, the Client may also be the sole Authorized User.
- 1.3 **Regulatory registration:** Certain Offerings may qualify as medical device software and may only be used in accordance with their intended purpose, applicable instructions for use, regulatory status, and in the jurisdictions where such use is lawfully permitted. PlanOp® iSizing and PlanOp® Aortic are CE-marked medical device software compliant with Regulation (EU) 2017/745, intended exclusively for use in countries where the CE mark is recognized. PlanOp® Aortic is also registered in UK, Switzerland and Serbia. PlanOp® iSizing is also registered in UK and Switzerland. If practicing outside of these countries, Client and Authorized Users acknowledge that they should be using the medical device software for evaluation or demonstration purposes only, without any actual clinical use.

2 Definitions

- **Affiliate:** Any entity that directly or indirectly controls, is controlled by, or is under common control with a party.
- **Authorized User:** An individual, including a Client's employee, consultant, or third-party contractor, who is authorized by the Client to access and use the Offerings, provided the Client remains fully responsible for their compliance with these GCUS. An Authorized User may also be the Client where the Client is an individual acting in a professional capacity, including a self-employed healthcare professional.
- **Client:** Client means the legal or natural person acting in a professional capacity that orders, subscribes to, registers for, or otherwise accesses the Offerings, whether free or paid, including healthcare institutions, companies, private practices, and self-employed healthcare professionals. Where applicable, the Client may designate Authorized Users and remains responsible for their compliance with these GCUS.
- **Client Data:** All electronic data, content, or information submitted by Authorized Users on behalf of the Client to the Offerings or collected and processed by PrediSurge on the Client's behalf, excluding the Offerings themselves and information on Authorized Users.

- **Order:** The document or electronic record (e.g., purchase order, quotation, electronic confirmation, online subscription, account registration, or activation record) detailing the specific Offerings ordered, subscribed to, registered for, or otherwise made available to the Client, the scope of use, and, where applicable, the corresponding fees.
- **Service Level Agreement (SLA):** The document, if applicable, that defines PrediSurge's commitments regarding the availability and performance of the Platform.
- **Service Credit:** A credit of a specified amount (e.g., a percentage of fees) granted to the Client for PrediSurge's failure to meet a commitment defined in the SLA.

3 Ordering and Acceptance

3.1 Order Methods. The Client may obtain access to Offerings via the following methods:

a. Traditional Paid Order: By sending a purchase order or accepting a PrediSurge quotation.

b. Online Paid Order: By purchasing directly through the Platform interface.

c. Free Access Registration: By registering for, activating, or otherwise accessing Offerings or features that PrediSurge makes available free of charge through the Platform or another acceptance method made available by PrediSurge.

3.2 Acceptance and Delivery. The Client's and Authorized Users' access to the Offerings will only be granted once:

a. Traditional Orders becomes binding, when PrediSurge provides written acceptance, which may be by confirmation email or by providing initial access to the Offerings.

b. Online Paid Order is accepted, upon successful transaction processing on the Platform, subject to the payment conditions set forth in Section 4.

c. Free Access Registration is accepted, when the Client or its Authorized User completes the applicable registration or activation flow and PrediSurge makes the relevant free Offerings available. Free access may be subject to feature limitations, usage caps, storage limits, and other conditions communicated on the Platform or these GCUS.

3.3 Access to the Offerings may be subject to preliminary account verification, professional eligibility checks, and regulatory availability in the relevant country.

3.4 **Order of Precedence.** No terms of any purchase order, supplier agreement, or other business form used by the Client will supersede, supplement, or otherwise apply to these GCUS and annexes. These GCUS, together with the annexes and applicable Order, constitute the entire agreement.

4 Fees and Payment

- 4.1 Fees. The Client shall pay all fees specified in the accepted Order or displayed on the Platform. Some Offerings or features may be made available free of charge. Unless fees are specified in an Order or on the Platform, no fees are due for such free Offerings during the applicable free access period.
- 4.2 Traditional Order Payment Terms. For Traditional Orders, the payment terms are specified in the Quote or Order and are, by default, via wire transfer within thirty (30) days (Net 30) from the invoice date.
- 4.3 Online Order Payment Terms. For Online Orders, payment is due immediately. Payment may be made online using a credit card or via wire transfer.
- 4.4 Free Access Terms. Free Offerings may be limited by functionality, number of Authorized Users, volume, storage, geography, intended use, duration, or other criteria specified by PrediSurge. PrediSurge may modify, suspend, or discontinue any free Offering or free feature at any time, subject to applicable law
- 4.5 Upgrade to Paid Offerings. The Client may upgrade from free access to paid Offerings through Ordering methods set out in Section 3. Fees for the paid Offerings will apply from the date the applicable paid Order is accepted. Upon upgrade, the Client's use of the upgraded Offerings will be governed by these GCUS, the applicable paid Order, and any plan-specific terms then in effect.
- 4.6 Taxes. All fees are exclusive of all taxes, duties, and levies, and the Client shall be responsible for payment of all such charges, excluding taxes based on PrediSurge's income.
- 4.7 Late Payment and Suspension. Any amount not paid when due will be subject to interest at one and a half times (1.5x) the legal interest rate in force in France, calculated from the due date until full payment is received. PrediSurge reserves the right to suspend or terminate the Client's access to the Offerings until all overdue amounts are paid in full.

5 License Grant and Ownership

- 5.1 License to Client. Subject to these GCUS and the applicable Order, including any Free Access Registration, PrediSurge grants the Client a non-exclusive, non-transferable, non-sublicensable right to access and use the Offerings during the applicable term solely for the Client's professional activities, including clinical planning, clinical support, evaluation, research, demonstration, and training purposes, in each case strictly within the intended purpose of the relevant Offering, the applicable product documentation, and the laws and regulations applicable in the jurisdiction of use.
- 5.2 Ownership. All rights, title, and interest in and to the Offerings (including the Platform and underlying software, code, brand, marketing support and intellectual property) are and will remain exclusively with PrediSurge and its licensors.
- 5.3 Client Data. The Client retains all ownership rights in and to the Client Data.

6 Use of Offerings

- 6.1 The Client may access the Offerings directly as an individual professional user or may designate Authorized Users to access the Offerings on its behalf, subject to the scope permitted under the applicable Order. Authorized Users may create accounts where permitted by PrediSurge. The Client remains responsible for monitoring its Authorized User's account(s), their authorization and their compliance with these GCUS.
- 6.2 Authorized Users must ensure that they use secure credentials, keep them confidential and contact Support at the shortest notice if they suspect their credentials being used without their authorization to access or use Offerings.
- 6.3 Authorized Users may use the sharing feature provided by PrediSurge to initiate on behalf of the Client the sharing of specific items of Client Data to other Authorized Users, where the Client has authorized such sharing and all legal requirements in §6 in Annex A – DPA are met. The receiving Client and the Authorized Users under its responsibility are responsible for any processing performed on the shared Client Data after such data has been made available to its Authorized Users through the sharing feature, including compliance with applicable healthcare regulation, data protection, confidentiality and medical secrecy obligations.

7 Restrictions on Use

The Client will not, and will not permit any Authorized User or third party to:

- a. Reproduce, modify, adapt, or create derivative works of the Platform or underlying software;
- b. Rent, lease, distribute, sell, sublicense, transfer, or provide access to the Offerings to a third party (other than an Authorized User);
- c. Reverse engineer, decompile, or disassemble the Offerings, except and only to the extent that such activity is expressly permitted by applicable law notwithstanding this limitation;
- d. Use the Offerings for illegal, harmful, or prohibited activities;
- e. Post, upload or share content which is inappropriate (harmful, sexually explicit, threatening, violent, fraudulent), violates third-party rights, includes malware (including viruses, bots, worms, scripting exploits), may damage people health.
- f. Share access credentials or use any access key, ID, or password provided to an individual to permit multiple individuals to use the Offerings.
- g. Use the Offerings for clinical purposes in regions where they are not regulatory compliant.

8 Client Data

- 8.1 Right to Use Data. Subject to these GCUS, the Client hereby grants to PrediSurge a non-exclusive, worldwide, royalty-free right to collect, use, copy, store, transmit, modify, and create derivative works of the Client Data, solely to the extent necessary to provide the applicable Offerings to the Client and to improve the Offerings.
- 8.2 Client Responsibility. The Client, and Authorized Users on behalf of the Client, represent and warrant that: (a) all necessary rights and permissions were obtained to provide the Client Data to PrediSurge and to grant the rights granted herein; and (b) the Client Data and its transfer to and use by PrediSurge as authorized by the Client do not violate any applicable law or third-party rights.

9 Data Protection and Security

- 9.1 Data Processing Addendum (DPA) - To the extent that PrediSurge processes personal data on the Client's behalf, the terms of PrediSurge's Data Processing Addendum (the "DPA") are hereby incorporated in **Annex A** by reference and shall automatically apply to all such processing.
- 9.2 Privacy policy - Processing of Authorized User personal information by PrediSurge as data controller is detailed in **Privacy Policy**.
- 9.3 Security Measures - PrediSurge shall maintain and implement technical and organizational security measures to protect Client Data in accordance with its Security Measures policy, which shall be based on industry best practices and standards. PrediSurge is not responsible for the security, integrity, use or further disclosure of shared Client Data once such data has been exported, downloaded, copied or otherwise processed by the receiving Client outside the Offerings.
- 9.4 Offerings may include Artificial Intelligence (AI). Design and security measures of AI included in Offerings are detailed in AI policy in **Annex E**.

10 Warranties and Disclaimer

- 10.1 Mutual Warranties. Each party represents and warrants that it has the legal power and authority to enter into these GCUS.
- 10.2 PrediSurge Limited Performance Warranty. PrediSurge warrants, for the Client's benefit only, that it uses commercially reasonable efforts to prevent the introduction of viruses, Trojan horses, or similar harmful materials into the Offerings.
- 10.3 Disclaimer. EXCEPT FOR THE LIMITED WARRANTY IN SECTION 10.2, THE OFFERINGS ARE PROVIDED "AS IS." PREDISURGE AND ITS SUPPLIERS EXPRESSLY DISCLAIM ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. PREDISURGE DOES NOT WARRANT THAT THE OFFERINGS WILL BE ERROR-FREE OR OPERATE WITHOUT INTERRUPTION.

11 Service Level and Support

- 11.1 Service Level Commitment. PrediSurge's commitment to Platform availability and performance, if any, shall be set forth in a Service Level Agreement (SLA) in **Annex D** or attached to the Order. Unless expressly stated otherwise, the SLA does not apply to free Offerings or free access periods.
- 11.2 Service Credits. If PrediSurge fails to meet the Service Level Commitment, the Client will be eligible to receive a Service Credit, calculated and applied in accordance with the terms of the SLA. Service Credits are not available for free Offerings or free access periods unless expressly stated otherwise.
- 11.3 Exclusive Remedy. The remedies specified in the SLA (i.e., Service Credits) are the Client's sole and exclusive remedy for any failure by PrediSurge to meet the availability or performance standards set forth in the SLA.
- 11.4 Support. PrediSurge commits to respond to any support request submitted by a Client or Authorized User within two (2) business days after receipt of a Notification. This support commitment does not apply to free Offerings or free access periods.

12 Indemnification

- 12.1 PrediSurge Indemnity. PrediSurge will defend the Client against any third-party claim that an Offering, used within the scope of these GCUS, infringes or misappropriates any third party's patent, copyright, or trademark, and PrediSurge will pay the amount of any resulting final judgment or negotiated settlement. PrediSurge's obligations are conditioned on the Client promptly notifying PrediSurge of the claim.
- 12.2 Client Indemnity. The Client will defend PrediSurge against any third-party claim arising from: (a) the Client Data, including its transfer and processing as authorized herein; or (b) the Client's or any Authorized User's breach of the restrictions on use set forth in Section 7, and the Client will pay the amount of any resulting final judgment or negotiated settlement.

13 Term and Termination

- 13.1 Term – These GCUS are binding from the date the Client and Authorized Users accept it and expire when all access to the Offerings has ended, including any free or paid Orders or registrations.
- 13.2 Standard termination – The Client, acting as a professional, may terminate free or paid access to the Offerings at any time by notifying PrediSurge Support. For paid Orders, if the termination request is submitted within 15 days following the initial Order, PrediSurge may, at its discretion, issue a refund for the corresponding Order. If the termination request is submitted after the 15-day period, no refund shall be granted, and all outstanding amounts related to current Orders and Offerings shall become immediately due and payable upon termination.
- 13.3 Termination of Free Access by PrediSurge – PrediSurge may suspend or terminate free Offerings or free access at any time, including but not limited to in the event of misuse, breach of these GCUS, inactivity, or discontinuation of the relevant free Offering, subject to applicable law.
- 13.4 Termination for cause – The Client and PrediSurge may terminate an Order and this GCUS if the other party: (a) fails to cure a material breach of this Agreement (including a failure to pay fees) within 30 days after notice, (b) ceases operation without a successor, or (c) seeks protection under a bankruptcy, receivership, trust deed, creditors' arrangement, composition or comparable proceeding, or if such a proceeding is instituted against that party and not dismissed within 60 days. If Client terminates for cause an Order or this GCUS, PrediSurge will refund to Client any pre-paid, unused fees for the terminated portion of the Order.
- 13.5 Effect of Termination – Upon expiration or termination of an Order and this GCUS: (a) Client's and Authorized Users rights to access and use the applicable Offerings will cease, (b) Client must immediately cease accessing and using the Offerings, and (c) PrediSurge will handle Client Data as detailed in DPA.
- 13.6 Clauses survival – Clauses 1, 2, 5, 8, 9, 10, 13, 15, 16 shall survive expiration of this GCUS.

14 Notifications

- 14.1 Notification should be sent in writing, in paper sent to PrediSurge office or in electronic format to :
- support@planop.ai for general support on Offerings
 - privacy@planop.ai for privacy related inquiries
 - orders@planop.ai for orders, and Quote and billing inquiries

15 Limitation of Liability

- 15.1 Consequential Damages Waiver. EXCEPT FOR EXCLUDED CLAIMS (AS DEFINED BELOW), NEITHER PARTY NOR ITS SUPPLIERS WILL HAVE ANY LIABILITY ARISING OUT OF OR RELATED TO THESE GCUS FOR ANY LOSS OF USE, LOST OR INACCURATE DATA, LOST PROFITS, FAILURE OF SECURITY MECHANISMS, INTERRUPTION OF BUSINESS, COSTS OF DELAY, OR ANY INDIRECT, SPECIAL, INCIDENTAL, RELIANCE, OR CONSEQUENTIAL DAMAGES OF ANY KIND, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, OR OTHERWISE.
- 15.2 Liability Cap. EXCEPT FOR EXCLUDED CLAIMS, EACH PARTY'S AND ITS SUPPLIERS' AGGREGATE LIABILITY TO THE OTHER ARISING OUT OF OR RELATED TO THESE GCUS WILL NOT EXCEED THE AMOUNT ACTUALLY PAID BY THE CLIENT TO PREDISURGE FOR THE OFFERINGS GIVING RISE TO THE LIABILITY IN THE TWELVE (12) MONTHS IMMEDIATELY PRECEDING THE DATE THE CLAIM AROSE.
- 15.3 Excluded Claims. "Excluded Claims" means: (1) amounts owed by the Client under any Orders; (2) either party's express indemnification obligations in Section 12; and (3) the Client's breach of Section 7 (Restrictions on Use).

16 Law and Jurisdiction

- 16.1 Governing Law. These GCUS, and all resulting disputes and claims, shall be interpreted and governed by French Law excluding the rules of the conflict of laws.
- 16.2 Dispute Resolution. All disputes occurring between the parties concerning or resulting from the existence, validity, interpretation, performance, and the termination of these GCUS (or one particular stipulation thereof) that the parties do not reach an amicable resolution in a period of thirty (30) days from the notification of the dispute shall be submitted to the exclusive jurisdiction of the competent International Court of Arbitration of Zürich or of its president acting in summary proceedings, notwithstanding the plurality of defendants or the activation of guarantees.

17 Changes to the GCUS

- 17.1 PrediSurge reserves the right to update or modify the GCUS and its annexes at any time, particularly to comply with legal or technical developments or changes in the Offerings. In the event of material changes, the Client and Authorized Users will be informed via an email notice at least 15 days prior to the applicable start date of the new GCUS version.
- 17.2 During this period, the Client and Authorized Users may refuse the amended GCUS, which may result in the termination of access to the Offerings, by notifying PrediSurge as detailed in section 13. Continued use of the Offerings after the effective date of the new GCUS shall constitute implied acceptance of the updated version.

ANNEX A – DATA PROCESSING ADDENDUM

This Data Processing Addendum (“**DPA**”) forms part of and is incorporated into the General Conditions Of Use and Sales (“**GCUS**”) between **PrediSurge** and the Client. It applies to all processing of personal data and/or protected health information (“**PHI**”) by PrediSurge on behalf of the Client. Processing of Authorized User personal information by PrediSurge as data controller is excluded from this DPA and is detailed in Privacy Policy.

1 Roles of the Parties

- 1.1 Controller / Processor Relationship - When the Client determines the purposes and means of processing, the Client acts as the Controller, and PrediSurge acts as the Processor. When the Client itself is processing data as a Processor for a third-party Controller, PrediSurge acts as a Sub-Processor.

2 Scope of Processing

- 2.1 PrediSurge will process the following categories of personal data on behalf of the Client:

- Medical images (DICOM format)
- Patient metadata (age, sex, internal identifiers)
- User account data
- Application logs and audit records
- Technical telemetry and analytics metadata

- 2.2 The processing operations are described in **Annex B**.

3 Client Instructions

- 3.1 PrediSurge shall process personal data only on documented instructions from the Client (which include GCUS, DPA), or as required to provide the Offerings under the GCUS or as required by applicable law.
- 3.2 PrediSurge will immediately notify the Client if an instruction clearly violates applicable law.

4 Subprocessing

- 4.1 The Client authorizes PrediSurge to engage subprocessors, including those located outside the European Economic Area, provided that:
- a. They are bound by written data protection terms at least as protective as this DPA.
 - b. PrediSurge maintains responsibility for their performance and security.
 - c. PrediSurge shall provide the Client with prior written notice of any intended changes concerning new subprocessors.
- 4.2 The list of approved subprocessors is provided in **Annex C**.
- 4.3 PrediSurge may transfer personal data, excluding PHI, outside the EEA to subprocessors, subject to an EU adequacy decision, Standard Contractual Clauses (SCCs), or other valid transfer mechanisms. PrediSurge shall perform a transfer impact assessment where required.

5 Security Measures

PlanOp® Platform and Offerings are included in the scope of the ISO27001 certification of PrediSurge and therefore benefits from the related security controls set in place in PrediSurge’s information security management system.

The infrastructure of PlanOp® Platform is hosted by Amazon Web Services (AWS), in a highly secure server environment located in Paris (France) with 24/7 assistance and monitoring to prevent unauthorized access and ensure data security, with AI algorithms running in Stockholm AWS datacenter. Advanced security measures, including firewalls, security agents, and monitoring, are in place to ensure continuous service and protection of

your data against natural disasters, intruders, and unforeseen events. To learn more about security in the AWS cloud, please visit <https://aws.amazon.com/security/>.

PrediSurge also implements by design in PlanOp® Platform a variety of security measures to protect the security, confidentiality, availability and integrity of personal information and any PHI when accessing Offerings, submitting personal information, or providing ClientCustomer Data when using Offerings. These security measures include for example:

- data encryption at rest and in transit,
- data backups,
- hosts redundancy,
- audit trails,
- user authentication,
- user rights management,
- vulnerability vigilance,
- and other industry-standard security practices.

PrediSurge employees may download data necessary to provide user with some Offerings or Support on on-premises workstations located in our offices in Saint-Etienne, France. Data is kept on the workstations only for the time of the processing and is deleted from this support right after being processed. PrediSurge implements a variety of security measures to protect the security, confidentiality, availability, and integrity of Customer Data when on its internal network. These security measures include for example:

- data encryption at rest and in transit,
- computer and server hardening,
- user authentication,
- VPN,
- firewall,
- network segregation,
- audit trails,
- vulnerability vigilance,
- and other industry-standard security practices.

All PrediSurge employees sign a non-disclosure agreement (NDA) and therefore commit not to disclose confidential data, especially any PHI they would access.

6 Case sharing feature in PlanOp® Platform

- 6.1 No default sharing - PrediSurge maintains strict segregation: by default, Client Data, PHI and personal data from one Client are not accessible to any other Client, and PHI and personal data from one Authorized User is not accessible to any other user.
- 6.2 Sharing between Authorized User - PrediSurge provides a feature enabling an Authorized User to initiate the sharing of specific items of Client Data, which may include PHI, to other Authorized Users which may belong to another Client. As between the source Client and the receiving third-party Client, each Client acts as an independent controller for its own processing activities relating to the shared Client Data, unless otherwise expressly agreed between such Clients.
- 6.3 When initiating a sharing using the sharing feature, the Authorized User acknowledges acting on behalf of the Client, bears the responsibility for determining whether it is permitted to share the relevant Client Data and shall ensure that :
 - any such sharing complies with applicable laws, data protection and regulatory requirements, especially when the sharing involves cross-border transfer to Clients outside the EEA and compliance with Chapter V of the GDPR,
 - the receiving Authorized User is authorized by its own Client and has a need to know,
 - appropriate contractual arrangements are in place with the third-party Client receiving the shared Client Data,
 - and sharing of PHI is strictly limited to what is necessary for the clearly defined lawful purpose and, where required under applicable law, is supported by an appropriate exemption, authorization or patient consent.

- 6.4 PrediSurge does not determine the purposes or legality of such data sharing and acts strictly in accordance with the Client's instructions. PrediSurge remains responsible for the processing activities listed in this DPA, including the security of Client Data during the sharing on the Platform (see §5 of this DPA). PrediSurge maintains appropriate records of processing activities.
- 6.5 Revocation - Client may revoke sharing access at any time by notifying PrediSurge and PrediSurge will remove access on the Platform by the receiving Authorized User to the shared Client Data within two business days upon request.

7 Confidentiality

PrediSurge guarantees that its personnel and subcontractors are bound by confidentiality obligations equivalent to those required under General Data Protection Regulation (« GDPR »).

8 Support

PrediSurge will provide reasonable and timely assistance to the Client to respond to requests for exercising a data subject's rights (including rights of access, rectification, erasure, restriction, objection, and data portability) in respect to personal data part of Client Data and for fulfilling Client's obligations under applicable privacy regulations.

9 Data retention and deletion

- 9.1 PrediSurge retains Client Data for 1 year after the end of processing. Offerings data derived from Client data (e.g., processing outputs required for regulatory/traceability purposes) are retained for 15 years.
- 9.2 Upon termination, PrediSurge deletes Client data within 90 days, unless retention is required by law. Logs, audit records and Offerings data derived from Client data may be retained as legally required.

10 Audits

Unless specified otherwise in a quote, upon entering into an NDA with PrediSurge, Client may audit PrediSurge's compliance by requesting reports from independent third-party auditors and/or internal auditors maximum once a year. PrediSurge will reasonably try to answer specific Client requests.

11 Breach Notification

PrediSurge shall notify the Client without undue delay and always within the timelines required by applicable laws of any confirmed personal data breach or PHI breach, including known details and mitigation steps.

ANNEX B – Details of Processing

Process name	User experience	Offerings monitoring	Offerings services
Personal data processed	Authorized Users personal information including: - surname, name, - email address, - company, healthcare institution, clinic, practice, or professional organization, - qualification, - and other information you choose to provide when using our website.	Authorized Users personal information including: - IP address, - browser type, - Internet Service Provider (ISP), - referral/exit pages, - platform type, - TLS fingerprint, - and date/time.	Client Data including : - images (de-identified images, in-vitro tests images) - physician or healthcare professional name and affiliated institution, clinic, or private practice, where applicable” - simulation input parameters (like proposed device reference).
Sensitive data processed	NA	NA	Client Data including : - medical images containing patient’s data - patient name, year of birth, sex
Purpose of processing	- Manage user accounts and access to PlanOp® Platform, - Personalize experience on our website, - Improve our website and services, - Contact via email to provide information regarding our products and services, - Respond to inquiries and requests for information. - Ensure security	- Analyze trends, - Administer the website, - Monitor website usage, - Ensure security.	Determined by the Client - Perform simulation service provision using PlanOp® Aortic software (CE marked), - Perform sizing and planning using PlanOp® iSizing (CE marked) - Conduct research within the frame of clinical studies. Client may share data for another purpose under its own responsibility of data controller.
Duration of processing	See section 9 of this DPA	See section 9 of this DPA	See section 9 of this DPA
Transfer to subprocessors	See section 4 of this DPA	See section 4 of this DPA	See section 4 of this DPA

ANNEX C – Subprocessor List

Subprocessor	Purpose of processing	Categories of personal data	Processing location
Amazon Web Services, Inc.	Cloud hosting	Client Data Authorized Users personal information	France, Sweden
Atlassian Corporation	Internal support ticketing	Authorized Users personal information	Germany
Theodo Cloud	Cloud monitoring and Health Data Hosting (French HDS regulation) compliance	Client Data Authorized Users personal information	France
Mailchimp	Email campaign management	Authorized Users personal information (email, name)	EU
Monday	Marketing automation, CRM	Authorized Users personal information, marketing data	EU
Hubspot	Marketing automation, CRM	Authorized Users personal information, marketing data	Germany
Microsoft Corporation	Marketing and sales analysis	Authorized Users personal information	France
Stripe	Online payment	Authorized Users personal information Credit card information	EU
Google Analytics	Aggregated (non-personal) product use analytics	Authorized Users personal information (company name, country)	World
Google Cloud	Captcha (security against bots)	Authorized Users personal information (IP address, browser type, referral/exit pages, platform type, TLS fingerprint and date/time)	World

ANNEX D – Service Level Agreement

1 Service Availability

PrediSurge will use commercially reasonable efforts to ensure that PlanOp® products available at planop.ai (PlanOp® Platform and PlanOp® iSizing) are available at least **99.5% of the time**, measured on a monthly basis (“Service Availability”).

2 Measurement

- 2.1 Downtime minutes (“Downtime Minutes”) are defined as the number of minutes during a calendar month when one of the products at planop.ai cannot be accessed by the Client and Authorized Users.
- 2.2 Service Availability is calculated by subtracting from 100% the percentage of Downtime Minutes (as defined above) out of the total minutes in the relevant calendar month.
- 2.3 Following service interruptions are excluded from Downtime Minutes :
 - a) Scheduled maintenance notified at least 24 hours in advance
 - b) Force majeure events
 - c) Issues originating from the Client’s network, systems, or third-party services not controlled by PrediSurge
 - d) Misuse of the products or use not in accordance with documentation

3 SLA Credits

If Service Availability falls below 99.5% in a given month, the Client may request a service credit within 30 days of the end of the affected month.

Service credits (applied to the next billing cycle):

Monthly Service Availability	Credit Provided
99.0% – 99.49%	1% of monthly subscription fees
95.0% – 98.99%	3% of monthly subscription fees
< 95.0%	5% of monthly subscription fees

Credits are the Client’s **sole and exclusive remedy** for failure to meet the SLA.

4 Request Procedure

Clients must submit their credit request to support@planop.ai, including:

- A description of the incident(s)
- The date and time of the observed downtime
- Any relevant logs or evidence (if available)

PrediSurge will evaluate the request and confirm eligibility within **10 business days**.

ANNEX E – AI policy

1 Purpose

This policy defines how Artificial Intelligence (AI) is developed, validated, deployed, and maintained within PrediSurge's medical software products (PlanOp® Aortic and PlanOp® iSizing). It ensures that AI use is **safe, ethical, transparent, and compliant** with applicable medical device regulations, while supporting healthcare professionals in delivering optimal patient care.

2 Scope

This policy applies to all AI models integrated in PrediSurge software as medical device products, specifically:

- **CT-scan processing models** that generate anatomical segmentation masks.
- **Simulation analysis models** that compute risk scores for endoleak (endoleak risk index aka ERI).

These AI models are integral parts of the medical devices and are governed by PrediSurge's ISO 13485-certified Quality Management System (QMS).

PrediSurge is provider of PlanOp® Aortic and PlanOp® iSizing software which are considered as high-risk AI systems according to EU AI act.

3 Guiding Principles

- **Patient Safety:** AI models are designed, validated, and monitored to protect patient safety.
- **Transparency:** Intended use, limitations, and performance characteristics of AI models are documented in product materials.
- **Reliability and Reproducibility:** AI models are fixed-version; outputs remain stable unless a product update is released.
- **Regulatory Compliance:** AI model development and deployment are part of our product development process and follow international standards and medical device regulations (e.g., ISO 13485, ISO 14971, IEC 62304, EU MDR, GDPR, FDA requirements).
- **Ethical Responsibility:** AI models are designed and used in ways that respect fairness, non-discrimination, and the integrity of clinical decision-making.

4 Model Development and Validation

- **Frameworks:** AI models are developed using widely adopted open-source machine learning frameworks, which are validated as part of our software development process. No third-party supplier of AI system is involved in the design, training and inference of our models. AI model design (model architecture, model choice, training process, data use) is recorded in product technical documentation.
- **Training Data:** AI models are trained exclusively on data from ethically approved clinical studies or publicly available datasets. Customer or patient data from product use is not used for training. Data used for training and validation is subject to data management plan to ensure its quality and the performance of AI models across the full range of intended use.
- **Version Control:** Each AI model is versioned and released only as part of a controlled product update, following QMS and regulatory processes. Data used for training and validation is also controlled and versioned.
- **Risk Management:** AI models and systems are included in our products' risk analysis to mitigate their safety and cybersecurity risk, maximize benefit-risk for the patient and inform end-user about residual risks.
- **Verification and Validation:** AI models and systems undergo rigorous internal validation, verification, and clinical performance assessment before release.
- **Performance Disclosure:** The validated performance of each AI system is documented in the product technical documentation. Performance information and residual risks of AI systems relevant for end-users are included in the *Instructions for Use (IFU)*.

5 Deployment and Use

- **Clinical Decision Support:** As stated in our product's *IFU*, AI system outputs support healthcare professionals; they do not replace clinical judgment.
- **Post-Market Surveillance:** AI system performance is monitored through customer feedback, complaint handling, and regulatory post-market processes.
- **Limitations:** Known limitations of the AI systems are clearly disclosed in product's *IFU* to ensure informed use.
- **Data Handling:** Customer data processed by the product remains fully under customer control.
- **Data Use:** User data resulting from product use is never used to train or validate AI models.
- **Cybersecurity and Privacy:** AI-related data handling and cybersecurity safeguards are covered by PrediSurge's *Privacy Policy* and follow state-of-the-art protection measures.

6 Ethics in AI

PrediSurge commits to the ethical use of AI in healthcare by adhering to the following principles:

- **Fairness and Non-Discrimination:** Training data is reviewed to minimize bias and ensure representativeness across relevant clinical populations and inclusion criterion detailed in product's *IFU*.
- **Transparency and Explainability:** AI system's purpose, functioning, and limitations are communicated to users in accessible terms.
- **Clinical Integrity:** AI systems are designed to augment — not replace — the expertise and judgment of healthcare professionals.
- **Accountability:** PrediSurge takes responsibility for the performance, safety, and compliance of its AI systems.

7 Governance and Oversight

- **Integration with QMS:** All AI systems lifecycle activities (design, development, validation, maintenance, risk management, and change control) are conducted under PrediSurge's ISO 13485 QMS.
- **Risk Management:** AI-related risks are identified, assessed, and controlled in accordance with ISO 14971.
- **Oversight:** AI activities are subject to internal reviews, audits, and regulatory inspections to ensure ongoing compliance.