

Processing Agreement for Usage of IPS Gate (PA)

It is agreed between

- "Customer" herein -

and

Karl Leibinger Medizintechnik GmbH & Co. KG
Kolbinger Straße 10
78570 Mülheim an der Donau

- "Contractor" herein -

1. Preamble

Upon entry into the main contract or with the binding request for manufacture of custom-made medical devices, the Customer engages the Contractor to process the Customer's personal data as a processor. This Processing Agreement ("PA" herein) concretizes the data protection obligations of the contracting parties in consideration of the requirements under Art. 28 of Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC of May 24, 2016 (General Data Protection Regulation – "GDPR" herein). It applies to all activities associated with the main contract, in the course of which individuals employed by the Contractor process personal data of the Customer.

2. Definitions

The terms used in this PA—such as "personal data," "processing," "controller," "processor" or "data subject" correspond with the definitions of the GDPR unless other definitions are included in this PA. "Data of the Customer" is exclusively understood to be such personal data which is either delivered by the Customer to the Contractor in connection with the main contract or collected and processed by the Contractor exclusively for the Customer on its behalf.

3. Subject matter and duration, nature, purpose and means of data processing

(1) The subject matter and duration of the processing, the nature, purpose and means of the processing as well as the nature of the personal data and the categories of the data subjects are set forth in **Attachment 1** of this PA.

(2) In the course of discharging the subject matter of the order in compliance with the requirements of this PA, the Contractor is entitled to execute all necessary processing steps with respect to the Customer's data (e.g. duplication of inventories for loss protection, creation of log files, intermediate files and staging areas), provided that this does not result in a transformation of the content of the Customer's data.

4. Duties of the Customer

(1) The Customer is solely responsible toward third parties for compliance with the provisions of the data protection laws applicable to the controller within the meaning of Art. 4 No. 7 GDPR; the duties of the Contractor and any rights of recourse or damages claims remain unaffected by this. The Customer itself shall independently assess whether the contract data processing and the order are permissible under data protection law. The Customer is responsible for discharging the controller's duties regulated in Articles 32 through 36 GDPR.

(2) The Customer shall promptly and completely inform the Contractor if it notices errors or irregularities with respect to the data protection requirements during its review of the order results.

(3) The Customer's contact person for data protection questions arising in the scope of the PA is named in **Attachment 1**. The Customer shall promptly inform the Contractor in text form concerning a change in the contact person.

(4) The Customer shall provide the Contractor all information which the Contractor needs to maintain the record under Art. 30 (2) GDPR.

(5) In case recourse is taken against the Contractor or the Customer by a data subject or by a body named in Art. 80 GDPR with respect to any claims under Art. 79 or 82 GDPR, the parties undertake to mutually support each other in defending the claims. In this context, both parties are authorized to disclose to third parties details of the PA, the data processing and of instructions of the Customer for purposes of defending such claims or for exculpation under Art. 82 (3) GDPR.

(6) After the main contract ends (see section 11 of this PA), the Customer must decide on the retention, surrender or deletion of the data of the Customer within a reasonable period set by the Contractor. If no decision reaches the Contractor within this period, the Contractor is entitled to delete such data unless the Contractor has legal obligations to retain the data (if applicable, in locked form).

(7) The following applies if the PA requires the Customer to pay for performances or to reimburse expenses: (i) with regard to the Contractor's personnel expenses, the daily rates stipulated in the main contract apply; If there is no such agreement, the daily rates customarily offered by the Contractor apply (ii) all other expenses, particularly performances by third parties, are charged along with a reasonable handling fee.

(8) The Customer shall promptly handle questions regarding the data processing legal requirements that cannot be finally resolved by the Contractor and regulate them by directive, if necessary.

5. Duties of the Contractor

(1) Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of the processing as well as the varying likelihood and severity of the risk to the rights and freedoms of natural persons, the Contractor shall implement technical and organizational measures in its area of responsibility for the reasonable protection of the data of the Customer that ensure the ongoing confidentiality, integrity, availability and resilience of the systems and services in connection with this processing and that have the ability to restore the availability of and access to personal data in a timely manner in the event of a physical or technical accident.

(2) The Contractor shall establish a process for regularly testing the effectiveness of technical and organizational measures for ensuring the security of the processing.

(3) The Contractor ensures that the employees concerned with processing the data of the Customer and other persons working for the Contractor shall process this data only in accordance with the instructions of the Customer unless they are legally obligated to do the processing. The Contractor further ensures that the persons it employs to process the data of the Customer have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality. This obligation shall also continue after completion of the order.

(4) The Contractor shall promptly notify the Customer if it becomes aware of breaches of the Customer's data. In such case, the Contractor can, provisionally and in its own discretion, implement appropriate measures in its area of responsibility to protect the Customer's data and mitigate possible adverse consequences. The Contractor shall inform the Customer as early as possible concerning any measures it has implemented.

(5) The Contractor's contact person for data protection questions arising in the scope of the PA is named in **Attachment 1**. The Contractor shall promptly inform the Customer in text form concerning a change in the contact person.

(6) If according to **Attachment 1**, the Contractor maintains a record of processing activities pursuant to Art. 30 (2) GDPR, it is authorized to supply the record pertaining to this PA to a supervisory authority or a third party at its request or the Customer may request this record from the Contractor if a supervisory authority demands this of it or the Contractor performs audits or certifications.

(7) Taking into account the nature of the processing and the information available to it, the Contractor shall assist the Customer in complying with the Customer's duties that are regulated in Articles 32 through 36 GDPR. The Contractor can demand reasonable compensation for this assistance and demand reimbursement of expenses unless otherwise agreed in the main contract.

(8) If the Customer's data at the Contractor is compromised through attachment or seizure, through insolvency or composition proceedings or through other events or third-party measures, the Contractor shall promptly inform the Customer of this unless the applicable law prohibits such information on important grounds of public interest.

6. Data secrecy, observance of the data protection provisions and principles

(1) The Contractor shall ensure that all persons (third parties or employees) who can obtain knowledge of the Customer's data shall process personal data exclusively on instruction or order (Art. 29 GDPR) and observe this PA. The Contractor may require corresponding evidence.

(2) The Contractor shall ensure that all persons (third parties or employees) who can obtain knowledge of the Customer's data are obligated to data secrecy. This obligation continues to exist under the GDPR for all persons named in the above sentence. The Contractor shall ensure that these persons are informed that personal data may not be processed without authority and that they may only process personal data lawfully (Art. 5 (1) a) GDPR) and must guarantee the confidentiality and integrity of personal data (Art. 5 (1) f) GDPR). The Contractor may require corresponding evidence.

(3) The Contractor shall keep all data of the Customer logically separate from its own data or third-party data. The Contractor shall destroy test and rejected material in accordance with data protection requirements. The Contractor is not authorized to create unauthorized copies of the personal data; excepted herefrom are required backup copies as well as electronic copies that are required to be created in fulfillment of the service contract.

7. Commitment to instructions

(1) Unless it is required by law to process the data, the Contractor may process the data of the Customer only within the scope of the main contract, including this PA, and the instructions of the Customer—also with regard to the transmission of personal data to a third country or an international organization in terms of Art. 4 (1) No. 26 GDPR (e.g. UN). In such case, the Contractor shall notify the Customer of these legal requirements in writing or by e-mail (text form), unless the applicable law prohibits such a notification on important grounds of public interest.

(2) "Instructions" are documented orders of the Customer that are focused on a specific processing of the Customer's data by the Contractor. They are initially set through this PA and can subsequently be modified, supplemented or replaced by the Customer through an individual instruction. Activities of the Contractor that are based on instructions which exceed the contractually stipulated scope of performance shall be additionally compensated by the Customer at cost.

(3) In principle, the Customer's instructions are to be issued in text form; oral instructions that may be necessary in exceptional cases shall be confirmed by the Customer in text form without delay. Persons with authority to issue instructions on behalf of the Customer and persons who are authorized to receive instructions on behalf of the Contractor shall be reported to the other respective party. The persons who are authorized accordingly on the effective date of this PA are listed in **Attachment 1**. The respective party shall promptly inform the other party in text form of a change in this person.

(4) The Contractor has no substantive legal duty to review instructions issued by the Customer. However, if the Contractor believes that an instruction from the Customer violates the GDPR or other data protection regulations of the Union or the member states, it shall promptly inform the Customer in text form. The Contractor is entitled to suspend performance of the contracted activity until the Customer has decided on the next steps and informed the Contractor in text form. The Customer shall bear any additional expenses of the Contractor that are occasioned through this. The Customer bears sole responsibility for its decision. If the Customer adheres to the issued instruction, which continues to seem an unlawful act to the Contractor, and demands that it be implemented, the Contractor is entitled (i) to condition the respective processing on the Customer's provision of security (e.g. guarantee) or (ii) to obtain a decision from the competent supervisory authority or (iii) to refrain from performing the processing.

(5) If due to the implementation of an instruction by the Customer (including those agreed to in the main contract) or of a decision under section (4) above, recourse is taken against the Contractor or its subcontractor by a third party claiming that the third party has incurred a tangible or intangible loss owing to a violation of the GDPR, or a supervisory authority has consequently fined or threatened to fine the Contractor or its subcontractor, the Customer shall indemnify the accused party in full from such claim or fine. The claim for indemnification shall also include the reasonable costs of the legal defense. The same shall apply when a claim is attributable to a breach of contractual or statutory duties by the Customer.

8. Engagement of subcontractors

(1) The Contractor is entitled to engage subcontractors as additional processors in accordance with the provisions made under section 12 of **Attachment 1**. The Contractor shall structure the contractual arrangements with the subcontractor in such a way that the same data protection obligations are imposed on the subcontractor with respect to the Contractor that are imposed on the Contractor in this PA, provided that no deviating obligations in favor of a subcontractor were agreed to in this PA. The above obligation expressly applies to the requirements for confidentiality, data privacy and data security in regard to the personal data. By written request, the Customer is entitled to receive information from the Contractor on the data protection obligations of the subcontractor.

(2) Should the subcontractor fail to meet its data protection obligations, the Contractor shall be liable to the Customer for compliance with that subcontractor's obligations as though the Contractor were personally at fault.

9. Notification, information and disclosure duties

(1) In terms of this PA, the Customer is responsible for observing the rights of data subjects provided in Chapter III of the GDPR. The Contractor shall assist the Customer to the extent possible with suitable technical and organizational measures for meeting its obligations in this respect. The Contractor can demand reasonable compensation for this assistance and demand reimbursement of expenses unless otherwise expressly agreed in the main contract.

(2) If a data subject contacts the Contractor to assert data privacy rights of data subjects that are regulated in the GDPR (such as claims for data portability, correction, deletion or information), the Contractor shall refer the data subject to the Customer if the information supplied by the data subject makes it possible to associate the data subject's inquiry with the Customer.

(3) The Contractor may issue information to third parties or to the data subject only after the Customer's prior consent.

(4) The Contractor shall correct, delete or lock the data processed under contract only after being instructed by the Customer to do so. If a data subject should contact the Contractor directly for the purpose of correcting or deleting the data subject's data, the Contractor shall promptly forward this request to the Customer for decision.

10. Contractor's evidence, inspections

(1) The Contractor shall provide the Customer evidence of its compliance with the duties set forth in this PA, as described under section 13 in **Attachment 1**, and make the necessary information for this available to the Customer.

(2) If data protection inspections or audits by the Customer or an independent external auditor engaged by the Customer—whose name is communicated to the Contractor sufficiently in advance—are necessary in individual cases (e.g. when the Customer has reasonable doubts about a self-audit submitted by the Contractor), they shall be performed on the Contractor's business premises in the presence of an employee of the Contractor during normal business hours and without disrupting operations following an announcement that allows for a reasonable lead time (normally at least four weeks). The Contractor may condition this on the signing of an appropriate non-disclosure agreement regarding the data of other customers and the established technical and organizational measures. If the auditor engaged by the Customer stands in a competitive relationship with the Contractor or its subcontractor, the Contractor may decline to be audited by the auditor.

(3) The Customer shall make a copy of the full audit report available to the Contractor in digital form. The Contractor may, in particular, also provide the audit report to its subcontractors.

(4) For assistance with the performance of the inspection or audit, the Contractor may require remuneration pursuant to section 4 (8) of the PA. The Customer's right to conduct an inspection or audit in accordance with paragraph (2) above is limited to one day per calendar year; deviations are to be agreed to with the Contractor in text form.

11. Return and deletion of data upon contract termination

(1) After termination of the main contract, the Contractor shall, if technically feasible and desired by the Customer in accordance with section 4 (7), return the Customer's data against remuneration of the associated expense. If desired and for remuneration of the associated expense, electronically stored data shall be returned either in a customary format on data media, with the Customer bearing the shipping risk, or transmitted to the Customer in encrypted form online, with the Customer bearing the transmission risk.

(2) In exchange for remuneration of the associated expense, the Contractor—in accordance with the processes defined in section 15 of **Attachment 1**—shall delete all electronically stored data of the Customer which the Customer does not wish to be returned pursuant to paragraph (1) or which is not technically feasible to return or, in the case of backups or log files, shall ensure that data processing is restricted up to the time of the deletion. The Contractor shall confirm the deletion to the Customer in text form.

(3) Data of the Customer which is not stored in electronic form (e.g. data on CDs, paper-based documents) and which the Customer does not wish to be returned pursuant to paragraph (1) shall be destroyed by the Contractor in compliance with data protection requirements against reimbursement of the associated expense. If requested, the Contractor shall provide the Customer evidence of destruction. The Contractor shall retain evidence of destruction for a period of one year.

(4) The obligation to return or delete data under this section 11 shall not exist if the Contractor is legally obligated to retain or otherwise store this data.

(5) If the Customer wishes its data to be retained beyond the contract end, a separate agreement between the parties is required. The parties shall agree on the corresponding performances and commercial effects and commit them to writing in a corresponding amendment agreement (this applies if the parties have agreed to an amendment process in the main contract).

12. Data protection officer

If the provisions of Art. 37ff. of the GDPR provide, the Contractor shall appoint a data protection officer to perform his work in accordance with the statutory guidelines. Such person's contact information shall be communicated to the Customer for the purpose of making direct contact.

13. Oversight of the Contractor and by the Customer

(1) If a data protection supervisory authority or other public supervisory authority of the Customer should perform an inspection at the Contractor, in principle, section 10 (2) and (4) first sentence of the PA apply accordingly. Signing of the confidentiality obligation is not required in this case.

(2) The contracting parties shall mutually inform each other without delay concerning all inquiries/orders and proceedings of government authorities, all measures of a body named in Art. 80 GDPR (such as complaints, warnings, assertion of claims) as well as all impending or ongoing judicial proceedings whose subject matter is the cooperation regulated in this PA, shall work closely in connection with such inquiries, orders, measures or proceedings and shall mutually make all required documents and information available. In this connection, each party is authorized to disclose all information and documents pertaining to this PA, including the details of the data processing, to its competent supervisory authority or to other third parties if such is necessary in the opinion of the party.

14. General provisions

(1) In the event of a conflict between the main contract and the PA, the provisions of this PA have priority. Unless deviating arrangements have been entered into in this PA, the covenants made between the parties in the main contract apply. This expressly applies to the termination and liability provisions entered into in the main contract. Should individual parts of this PA be invalid, this shall not affect the validity of the remainder of the PA.

(2) Amendments and supplements to this PA and its components are required to be in written form. This also applies to the waiver of this form requirement.

(3) The parties agree that German law shall apply to this PA, with exclusion of the rules of private international law. The exclusive judicial venue for all disputes arising under or in connection with this PA is at the domicile of the Contractor.

Attachment 1: Details on the order (if not described in the service contract)

Place, date

Place, date

Customer

**Karl Leibinger Medizintechnik GmbH
& Co. KG**

Please send this Agreement to:

Karl Leibinger Medizintechnik GmbH & Co.KG
Privacy Manager
Kolbinger Strasse 10
78570 Mühlheim
Germany

Or send as attachement to mail: privacy@klsmartin.com

Attachment 1: Details on the order (if not described in the service contract)

1.) Scope, nature and purpose of the planned collection, processing or usage of data:

The Customer shall transmit medical patient data to the Contractor by means of the IPS Gate platform. The purpose of this transmission is the production of individually manufactured medical devices, such as prostheses, for the Customer, which will in turn use them for the medical treatment of its patients.

Besides the processing of personal data for the manufacture of the medical devices, it may furthermore be necessary for the Customer's personal data to be processed for the purpose of delivery of the customized products.

2.) Duration of the processing

Personal data is processed in each case only on an order-related basis and only while it is needed to render the contractual performance and comply with legal obligations.

3.) Nature of the data:

- ☐ Personal master data
- ☐ Communication data (e.g. telephone, e-mail)
- ☐ Contract master data (contractual relationship, interest in product or contract)
- ☐ Contract billing and payment data
- ☐ Planning and management data
- ☐ Information (from third parties, such as credit agencies, or from public records)
- ☐ Medical data
- ☐ Other:

4.) Sphere of data subjects:

- ☐ Customers
- ☐ Interested parties
- ☐ Contact persons
- ☐ Patients
- ☐ Other:

5.) Customer's persons who are authorized to issue and receive instructions and supervise

Last name	First name	Address	E-mail

6.) Contractor's persons who are authorized to receive instructions

Last name	First name	Address	E-mail
Schmider	Christian	Kolbinger Straße 10, 78570 Mühlheim	Christian.Schmider@klsmartin.com

7.) Contact persons for data privacy questions of the Customer arising under the agreement

Last name	First name	Address	E-mail

8.) Contact persons for data privacy questions of the Contractor arising under the agreement

Last name	First name	Address	E-mail
Johs	Andreas	Kolbinger Straße 10, 78570 Mühlheim	privacy@klsmartin.com

9.) Any notifications of the Contractor in regard to Art. 28 (3) a) GDPR

10.) Time period under section 4 (7) of the PA

After a written request by the Contractor, the Customer must decide within a fourteen-day period on the surrender or deletion of the data following termination of the main contract.

11.) Record of processing activities pursuant to Art. 30 GDPR

The Contractor is obligated to maintain a processing record pursuant to Art. 30 GDPR.

12.) Engagement of subcontractors

(1) The use of subcontractors as additional processors is only permitted if the Customer issues advance consent in text form.

(2) At the time of entry into the contract, the Customer issues its consent that the partial performances described below shall be performed through engagement of the following subcontractors.

a) 1. Subcontractor

Name: alliT GmbH

Address: Technologiepark 17, A-4320 Perg

Description of the partial performance: hosting the IT systems Certified and TÜV-tested.

b) 2. Subcontractor

Name: CADS GmbH

Address: Technologiepark 17, A-4320 Perg

Description of the partial performance: further development of the IPS Gate software platform

(3) Before enlisting additional or replacing the listed subcontractors, the Contractor shall obtain the Customer's consent, which may not be refused absent an important data protection reason.

(4) The Contractor shall take Art. 44ff. GDPR into consideration when concluding any contracts with subcontractors, particularly on the basis of EU standard contracts. If and when data is collected and/or used by the subcontractor outside the EU or the EEA, the Customer hereby authorizes the Contractor to enter into the "Controller to Processor" EU standard contract with the subcontractor by proxy for the Customer in the form that either (i) the Customer enters into an existing EU standard contract between the subcontractor (as processor) and the Contractor (as controller) and in this respect acquires the same rights as the Contractor under the EU standard contract or (ii) the Customer enters into an EU standard contract directly with the subcontractor and the Contractor enters into this so that in this respect it acquires the same rights as the Customer under the EU standard contract.

13.) Deletion

Pursuant to section 11 (2) of the PA, the process of the deletion of electronically stored data is structured as follows:

Personal data is deleted in compliance with legal obligations, if this is necessary.

Personal data for which no order is subsequently placed because the Customer's order is not received is automatically deleted and logged in ninety days.