
Contract Data Processing Agreement
pursuant to Art. 28 (3) of the General Data Protection Regulation (GDPR)

between

– hereinafter referred to as the “Client” –

and

Heidelberg Engineering GmbH

Max-Jarecki-Straße 8

69115 Heidelberg

Germany

– hereinafter referred to as the “Contractor” –

Date: _____

Contract Data Processing Agreement

Preamble

- (1) The Contractor renders services to the Client in connection with the Contractor's medical technology products on the basis of separate Service Agreements. The provision of these services may potentially cause the Contractor to come into contact with personal data that are processed by the Client as the controller in the meaning of Regulation (EU) 2016/679 ("GDPR"). The Parties desire for this Agreement to ensure that the Contractor renders its services as a processor by being bound to the Client within the meaning of Article 28 (3) sentence 1 GDPR.
- (2) Insofar as the Client is engaged as a processor by a third party as the controller and in this case uses the Contractor as a sub-processor for the provision of services for this third party, this Agreement shall also apply to all activities within the scope of the Service Agreements in which employees of the Contractor or further processors engaged by the Contractor process personal data which the Client processes as a processor for this third party.
- (3) The provisions stipulated in this Agreement supplement the Service Agreements currently in place between the Parties, as well as those to be concluded in the future.
- (4) Upon coming into effect, this Agreement replaces all contract data processing agreements previously concluded between the Contractor and the Client in connection with the relevant Service Agreements.

Clause 1 - Object and duration of contract data processing

- (1) The contract data processing is carried out by the Contractor as an activity bound by instructions in accordance with the provisions stipulated in the following on behalf of the Client.
- (2) Insofar as the Client is itself the controller within the meaning of Art. 4 No. 7 GDPR, the Client shall be solely responsible within the scope of this Agreement for compliance with the statutory provisions of the data protection laws, in particular for the lawfulness of the transfer of data to the Contractor as well as for the lawfulness of the data processing.
- (3) Insofar as the Client acts as a processor for a third party as the controller, the third party shall be solely responsible within the scope of this Agreement for compliance with the statutory provisions of the data protection laws, in particular for the lawfulness of the transfer of data to the Contractor as well as for the lawfulness of the data processing.
- (4) The subject matter of the contract data processing is the provision of the agreed services and the performance of the processing of personal data related to these services. Details are specified in **Annex 1**.
- (5) The duration of the contract data processing results from the individual Service Agreements with the Client.

Heidelberg Engineering GmbH
Max-Jarecki-Str. 8
69115 Heidelberg
Germany

Phone +49/62 21/64 63-0
Fax +49/62 21/64 63 62
www.HeidelbergEngineering.com

Managing Directors
Arianna Schoess Vargas
Kfir Azoulay

Mannheim HRB 334163

Clause 2 - Description of the contract data processing

- (1) The nature and the purpose of the contract data processing are specified in **Annex 1**.
- (2) The type of personal data and the categories of data subjects are specified in **Annex 1**.

Clause 3 - General provisions governing the Client's rights and obligations

- (1) The Client shall inform the Contractor without undue delay if the Client detects errors or irregularities during the inspection of the contract data processing, occasionally during the audit pursuant to Clause 11 - *Client's audit, access and information rights*, or in any other way.
- (2) In exercising its authorities resulting from this Agreement, the Client shall give consideration to the rights, legal interests and other interests of the Contractor.
- (3) In order to enable the Contractor to exercise its information obligations under this Agreement, the Client provides the email address to be used in **Annex 3**. The Contractor shall be notified without undue delay of any change in the email address.

Clause 4 - Client's right to issue instructions

- (1) The Contractor undertakes to carry out the contract data processing in strict adherence to the contractual stipulations, which the Client may in individual cases specify in more detail by issuing instructions. The right to issue instructions extends to the decision whether data processing will take place and which data are to be processed by the Contractor. The decision about the means of data processing is made at the Client's sole discretion; however, a contractual obligation to carry out the data processing by certain means or in a certain way is subject to the Parties' prior agreement that must also provide for the corresponding consideration payable by the Client. The right to issue instructions does not extend to the technical and organizational measures to be implemented by the Contractor and is generally limited to the stipulations of this Agreement.
- (2) The Client shall issue its instructions concerning the contract data processing to the Contractor in text form and document their issuance. The Client shall direct its instructions to the Contractor's management personnel or to an instruction recipient specified in **Annex 1**. The Client's management personnel and any employee of the Client authorized for this purpose are authorized to issue instructions.
- (3) The Contractor shall inform the Client if, in the opinion of the Contractor, an instruction of the Client infringes applicable data protection law (objection). The Contractor is entitled to suspend the execution of an objected instruction until the Client has reviewed the objected instruction and confirmed to the Contractor that it is to be executed. A confirmation shall only be effective if it is communicated at least in text form, and its issuance shall also be documented by the Client.

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Phone +49/62 21/64 63-0
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- (4) The Contractor is authorized to carry out data processing beyond the contractual stipulations in as far as the Contractor is required to do so by Union or Member State law to which the Contractor is subject. In such a case, the Contractor shall inform the Client of that legal requirement before carrying out such data processing, unless the relevant law prohibits such information on important grounds of public interest.

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Clause 5 - Contractor's general obligations

- (1) The Contractor shall only engage those employees or other persons for data processing who have been obligated to maintain confidentiality and data secrecy with reference to the consequences under regulatory and criminal law.
- (2) The Contractor shall implement technical and organizational measures to ensure that the employees or other persons who have access to personal data from the Client's area of responsibility only process such data within the scope of the contractual stipulations, unless they are required by law to process such data in another way. In such a case, the Contractor shall inform the Client of that legal requirement as soon as the Contractor becomes aware of the intended or completed carrying out of such data processing, unless the relevant law prohibits such information on important grounds of public interest.
- (3) The Contractor shall designate a Data Protection Officer who exercises his/her tasks in accordance with Articles 38 and 39 GDPR, if the Contractor is legally obligated to do so. The contact details of the Data Protection Officer are communicated to the Client for the purpose of direct contact in **Annex 2**. A change of the Data Protection Officer shall be communicated to the Client without undue delay.
- (4) The Contractor confirms its knowledge of the data protection regulations of the GDPR relevant for the contract data processing.

Clause 6 - Protection of private secrets (Section 203 of the German Criminal Code)

- (1) The Contractor is hereby obligated by the Client to maintain secrecy pursuant to Section 203 (4) sentence 2 no. 1 StGB (German Criminal Code).
- (2) The Contractor shall obligate the persons employed by the Contractor, who are involved in the fulfillment of the Service Agreements with the Client, in written form to maintain secrecy in accordance with § 203 StGB.

Clause 7 - Data security concept

- (1) The Contractor undertakes to implement and maintain the technical and organizational measures set out in the Contractor's data security concept within the scope of the contract data processing. The data security concept valid at the time of signing this Agreement can be accessed by the Client on the website <https://www.heidelbergengineering.com/int/AVV/>.
- (2) The Contractor is authorized to update the data security concept by unilateral amendments and then to implement corresponding technical and organizational measures. The Client has access to the latest valid version of the data security concept at any time on the website <https://www.heidelbergengineering.com/int/AVV/>.

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Updates must in particular be carried out due to changes in the statutory framework conditions, as well as requirements from courts or public authorities that are imposed on the Client, the Contractor or another customer of the Contractor who uses the same standardized services rendered by the Contractor, and that necessitate an amendment. Individual measures previously contained in the data security concept may be omitted by updates without having to be replaced by similar measures. A planned update of the data security concept by the Contractor is not permitted if it would cause the overall level of protection afforded by the measures under the current data security concept to deteriorate immediately prior to the planned update.

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Germany

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Fax +49/62 21/64 63 62
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- (3) The Contractor's authority to update the data security concept does not affect the Client's sole responsibility to evaluate the measures set out in the data security concept and the level of protection warranted by them. The Contractor is not required to advise the Client with regard to the suitability and necessity of measures in the meaning of Article 32 (1) GDPR. The Client's requests for changes to the data security concept and the measures to be implemented by the Contractor thereupon shall not be unreasonably declined by the Contractor if the Client has agreed to bear the costs arising from the realization of its change requests.

Clause 8 - Engagement of other processors

- (1) The Contractor shall generally be permitted to have its services rendered by other processors.
- (2) The Client has authorized the list of other processors available on the website <https://www.heidelbergengineering.com/int/AVV/> at the time of signing this Agreement.
- (3) The Contractor shall notify the Client about any intended engagement, change with regard to the engagement or replacement of other processors within due time to allow the Client to object within ten working days from receipt of the notification. Both the notification as well as the objection require at least the text form in order to be legally effective. The objection further requires the statement of a reason. The Client has access to the latest valid version of the list of other processors engaged by the Contractor at any time on the website <https://www.heidelbergengineering.com/int/AVV/>.
- (4) If the objection is received by the Contractor in due time and states a reason, the Contractor shall make reasonable efforts to provide the Client with an adjustment of the respective affected services or to propose a commercially reasonable adjustment of the utilization of the respective affected services in order to avoid processing of personal data by the objected further processor without unreasonably burdening the Client. If the Contractor is unable to make such adjustment within a reasonable period of time not exceeding thirty days, the Client is entitled to terminate the Service Agreements with the Contractor with a notice period of fourteen days. If the Client does not exercise its right to early termination, the Client's consent will be deemed to have been granted.

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Arianna Schoess Vargas
Kfir Azoulay

Mannheim HRB 334163

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- (5) Data processing operations to be carried out by the intended engagement of another processor may be postponed by the Contractor for the duration of the objection period in order to await the Client's decision.
- (6) The Contractor shall be obligated to comply with the requirements stipulated in Article 28 (4) GDPR.

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Germany

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Clause 9 - Performance of the rights of data subjects

- (1) If the Client or the third party for which the Client is acting as a processor is obligated as a controller to a data subject under applicable data protection law, the Contractor shall support the Client in the performance of its obligations, if and to the extent that actions of the Contractor are in fact indispensable for this purpose and to the extent that such cooperation can reasonably be expected from the Contractor.
- (2) If a data subject contacts the Contractor directly with inquiries or claims, the Contractor shall refer the data subject to the Client. If and to the extent that the Contractor is obligated towards the data subject by law in connection with the contract data processing, the Contractor shall inform the Client about the satisfaction of legitimate claims asserted by such data subject.

Clause 10 - Contractor's obligations to provide information

- (1) The Contractor shall inform the Client about measures taken by the data protection supervisory authority as well as about investigative measures conducted by prosecution authorities at the Contractor's place of business with regard to the suspicion of the commission of criminal acts under data protection law, insofar as the processing of personal data from the Client's area of responsibility is affected by the measures.
- (2) If the Contractor becomes aware of a personal data breach, the Contractor shall inform the Client of this personal data breach without undue delay, provided that the data affected by the personal data breach originate from the Client's area of responsibility. In doing so, the Contractor shall disclose everything of which the Contractor is positively aware and shall make subsequent notifications as soon as further information becomes known.
- (3) If the Client has to conduct a data protection impact assessment and, if applicable, a prior consultation, the Contractor shall support the Client in fulfilling its obligations, if and to the extent that actions of the Contractor are in fact indispensable for this purpose and to the extent that such cooperation can reasonably be expected from the Contractor.

Clause 11 - Client's audit, access and information rights

- (1) The Client is authorized to obtain information from the Contractor to prove compliance with the obligations stipulated in Art. 28 GDPR and in this Agreement and conduct audits at the Contractor for this purpose.

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- (2) Such audits shall be carried out regularly by obtaining a self-assessment from the Contractor. The Contractor is authorized to supplement or substitute the self-assessment with copies of audit certificates or third-party certifications, provided these are not older than one year. The audit certificates or certifications must also relate to the technical and organizational measures contained in the data security concept valid at the time of the Client's audit.
- (3) In the event of factually justified doubts as to the correctness or completeness of the statements in a self-assessment or in test certificates or certifications as well as in the event of the existence of an important reason (e.g. follow-up review directly after notifying the Contractor pursuant to Clause 10 - *Contractor's obligations to provide information*), the Contractor undertakes to accept an on-site inspection to be carried out. For these cases and for this purpose, the Contractor grants the Client the right, after timely notification, to inspect the Contractor's business premises during ordinary office hours without causing any significant interference with the Contractor's business operations to ensure compliance with the contractual requirements and the obligations resulting from Article 28 GDPR. The Client may request information required for this purpose only from the Contractor's management and only to an extent that is reasonable for the Contractor.
- (4) The Client may only exercise the inspection, access and information rights pursuant to this Clause itself, through its own employees or through external auditors to be mandated by the Client at its own expense. The specific person shall be announced by name in advance. Only persons professionally bound to secrecy may be considered as external auditors and this only if the Client proves to the Contractor prior to the start of the audit that the Client has agreed with the respective professional secrecy holder that the inclusion of the Contractor in the scope of protection of the professional secrecy obligations cannot be revoked without the Contractor's involvement.
- (5) The Client must document the on-site inspection carried out and the findings thereof in a timely manner and furnish the Contractor with a full copy of the documentation without undue delay upon completion.

Clause 12 - Termination of the Agreement

- (1) Upon termination of this Agreement – irrespective of the legal reason for the termination – the Contractor shall delete or destroy all data originating from the Client's area of responsibility that are still in the Contractor's possession, unless and to the extent that the Client instructs the Contractor to return such data upon termination of this Agreement or immediately thereafter at the latest.
- (2) The Contractor is authorized to refrain from carrying out such deletion or destruction as well as return of the data by way of exception, if and to the extent legal requirements prevent the Contractor from doing so. The Contractor shall inform the Client of such legal requirements, unless the relevant law prohibits such information on important grounds of public interest.

Heidelberg Engineering GmbH
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- (3) Until all personal data processed on behalf of the Client and still in the possession of the Contractor after the termination of the Service Agreements have been deleted or destroyed by the Contractor or returned to the Client, this Agreement shall be deemed to continue to be in effect even after the termination of the Service Agreements – irrespective of the legal reason for the termination. Upon the lapse of the condition stipulated in the preceding sentence, this Agreement shall terminate without requiring a separate declaration by either party.

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Germany

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Clause 13 - Contractual components, precedence of documents

- (1) The following Annexes form an integral part of this Agreement:
- **Annex 1** - Supplemental Provisions to the Contract
 - **Annex 2** - Contractor's Data Protection Officer
 - **Annex 3** - Client's Data Protection Officer and Email Address
- (2) In addition, the data security concept and the list of other processors, both made available on the website <https://www.heidelbergengineering.com/int/AVV/>, form an integral part of this Agreement.
- (3) The provisions stipulated in this Agreement take precedence over all other agreements between the Parties.

For the Client:

For the Contractor:

Date

Name in printed letters

Position

Signature

Arianna Schoess Vargas

Name in printed letters

Managing Director

Position



Signature

Managing Directors
Arianna Schoess Vargas
Kfir Azoulay

Mannheim HRB 334163

Annex 1: Supplemental Provisions to the Contract

Heidelberg Engineering GmbH
Max-Jarecki-Str. 8
69115 Heidelberg
Germany

Subject matter, nature and purpose of the contract data processing / instruction recipients

Phone +49/62 21/64 63-0
Fax +49/62 21/64 63 62
www.HeidelbergEngineering.com

Sales and Academy	
Subject matter	<p>Provision of training services and other services for demo or loan, rentals and purchases of the Contractor's medical technology products (software and devices as well as their peripherals such as computers, printers, etc.). Support for work within the scope of patient management.</p> <p>Commissioning of Contractor's medical technology products (software and devices as well as their peripherals such as computers, printers, etc.) and provision of installation and basic support services for these medical technology products.</p>
Nature	<p>Demonstration and user training directly on the device or with the software, partly with the involvement of patients.</p> <p>For basic support services:</p> <ul style="list-style-type: none"> • Function checks • Minor repairs/troubleshooting • Software installation/update and configuration • User support and assistance <p>The data processing takes place via telephone, email, remote access or on site at the Client's premises or at the premises of a third party as the controller.</p>
Purpose	<p>Learning how to safely operate the Contractor's medical technology products. Obtaining an official training certificate required to operate the medical technology product.</p> <p>Installation, preventive maintenance and servicing of the operability of the devices, systems and software of the Client or of the third party as the controller. This also applies to demo or loan devices or rented devices.</p>
Instruction recipients	Clinical trainers resp. sales representatives

Service & Support and Project Management	
Subject matter	Provision of installation, maintenance and support services as well as consulting for the Contractor's medical technology products (software and devices as well as their peripherals such as computers, printers, etc.)

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Nature	<p>Among others:</p> <ul style="list-style-type: none"> • Function checks • Repairs/troubleshooting • Software installation/update and configuration • System integration with third-party software and hardware systems • User support and assistance • Analysis and optimization of workflows <p>The data processing takes place via telephone, email, remote access or on site at the Client's premises or at the premises of a third party as the controller and, if necessary, at the Contractor's premises.</p>
Purpose	Preventive maintenance and servicing of the operability of the devices, systems and software of the Client or of a third party as the controller.
Instruction recipients	Employees of the Service & Support department resp. of the Project Management Healthcare IT department.

Demo or loan as well as rental of devices	
Subject matter	<p>Deletion of all data collected by the Client or by a third party as the controller on the Contractor's systems in the course of a demo, loan or rental.</p> <p>Upon request of the Client, provision of the data collected by the Client or by a third party as the controller on the Contractor's systems in the course of a demo, loan or rental.</p>
Nature	<p>Execution of the data deletion.</p> <p>Upon request, prior backup of data located on the demo, loan or rental device and handover of the data backup to the Client or to a third party as the controller.</p> <p>The data processing takes place on site at the Client's premises or at the premises of a third party as the controller or at the Contractor's premises.</p>
Purpose	<p>Data protection compliant deletion of all data before the demo, loan or rental device is made available to another customer.</p> <p>Enabling the Client or a third party as the controller to further use the data collected in the course of the demo, loan or rental, should the Client or the third party not have been able to back up such data.</p>

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Instruction recipients	The employee of the Contractor who takes back the demo, loan or rental device or to whom it is sent by the Client.
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Categories of data subjects and type of personal data

The following information applies to all of the aforementioned contract data processing.

Categories of data subjects	<ul style="list-style-type: none"> • Employees of the Client resp. employees of a third party as the controller • Patients of the Client resp. patients of a third party as the controller
Type of personal data	<p>In the course of the provision of services, contact with all types of personal data of the aforementioned data subjects is possible and cannot be excluded with certainty. This includes among others:</p> <ul style="list-style-type: none"> • Names • Private and business contact information (e.g. postal addresses, email addresses, telephone numbers) • Insurance data • Log data • Patient data • Medical data (e.g. imaging data, analysis results, diagnoses, findings) • Performance parameters (e.g. data on measures, therapies and medications) • Billing and cost data

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Arianna Schoess Vargas
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Annex 2: Contractor's Data Protection Officer

Data Protection Officer designated by the Contractor	
Name	CL Compliance und Datenschutz GmbH & Co KG
Postal address	Douglasstraße 11 – 15 76133 Karlsruhe Germany
Contact information	Telephone: +49 (0) 721-91250880 Email: HeidelbergEngineering@compliance-datenschutz.de

Heidelberg Engineering GmbH
Max-Jarecki-Str. 8
69115 Heidelberg
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Annex 3: Client's Data Protection Officer and Email Address

Data Protection Officer designated by the Client (if available)	
Name	
Postal address	
Contact information	Telephone: _____ Email: _____
Client's email address (to enable the Contractor to exercise its information obligations towards the Client)	
Email address	

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