

Contractual arrangements and agreements for order processing (OPs)

in accordance with Article 28 GDPR (DSGVO)

Principal

HEINE Optotechnik GmbH & Co. KG

Order processing agreement - Rev. 00 -

Principal

User of the DERManager application

Contractor

HEINE Optotechnik GmbH & Co. KG

Dornierstr. 6
82205 Gilching, Germany

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Note regarding gender-neutral wording

A fair and equal society requires gender-neutral language. As far as is possible and sensible, appropriate wording will be used in the following text (e.g. gender-neutral pronouns and their derivatives). Terminology, definitions, citations and similar wording will not be replaced by gender-neutral pronouns. Such terms are to be interpreted in a gender-neutral way for the purpose of equality.

For the purposes of making this document easier to read, if a single gender is used for personalised nouns and pronouns, this similarly does not imply discrimination against other genders, but should be understood as gender neutral for the purpose of simplifying the language used.

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1. General

- 1.1. The contractor processes personal data on behalf of the principal. In accordance with the wishes of the parties, and particularly the principal, this agreement includes the written instruction for order processing according to Article 28 of the EU-GDPR (DSGVO) and governs the rights and obligations of the parties in connection with data processing.
- 1.2. If, in this agreement, the term "Data processing" or "Processing" (of data) is used, this is based on the definition of "Processing" according to Art. 4 No. 2 GDPR.

2. Object of the agreement

- 2.1 The digital management system HEINE DERManager is provided in the versions DERManager ('cloud server') or CUBE powered by HEINE DERManager ('on-premise server').

The principal's order to the contractor covers the following work and/or services (please select as appropriate):

- To make it possible to check whether existing data stored in the customer's legacy system is compatible with the DERManager system, the contractor will initially make their database available to the order processor for a **test migration**. Only when system compatibility has been positively established will the principal conclude an appropriate agreement with HEINE regarding the use of DERManager. This subsequently includes the transfer, for an indefinite period, of the HEINE DERManager software for non-exclusive use (this transfer being subject to a fee), the maintenance services for the software and the training and support services for adapting the software to the principal's specific requirements.

The contractor thus performs the following order processing:

The transfer of the principal's personal data from an external data medium (e.g. external hard drive) to the Cube cloud, to make it possible to check whether transferability exists.

- The contractor provides the DERManager service as part of a subscription. As part of the service, the principal's data is stored on a cloud server belonging to the contractor in the course of treatment documentation.

The contractor thus performs the following order processing:

HEINE stores the personal data for the principal on the cloud server to hold this data and make it accessible for the principal. In addition, HEINE provides support services for its customers in connection with DERManager (the cloud solution) via e-mail or telephone contact to enable problem analysis and fault resolution.

- The contractor makes the HEINE DERManager app available to the principal. The app is stored on the principal's mobile device. Within this app, the user can forward images created with a HEINE Dermatoscope to the DERManager system.

The contractor thus performs the following order processing:

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Transfer of the personal data to be stored from and to the DERManager system.

- The principal uses the DERManager on-premise solution, thereby making use of the contractor's support services.

The contractor thus performs the following order processing:

Support services via e-mail or telephone contact in connection with DERManager (on-premise solution), to enable problem analysis and fault resolution.

2.2 The following types of data are in general the object of processing:

Order processing involves the following categories of data:

- Personal master data (first name, surname, address, contact details, user codes and names, authorisations)
- Communication data (e.g. telephone, e-mail)
- User-related change logs
- Patient data (health data and patient history)
- Contract master data (contractual relationship, product and/or contractual interest)
- Contract billing and payment data
- Information data (from third parties, e.g. credit agencies or from public directories)
- Log data (IP addresses, browser identification, browser version)

2.3 Group of people affected by data processing:

- Business partners (suppliers, sales representatives)
- The principal's employees
- Patients
- Contacts

3 Rights and obligations of the principal

- 3.1. In accordance with Art. 4 No. 7 GDPR, the principal is the controller of the data subcontracted for processing to the contractor. Assessment of the legitimacy of data processing is solely incumbent on the principal. In accordance with clause 4. para 6, the contractor has the right to inform the principal if they believe that any data processing taking place is not permitted by law.
- 3.2. As the controller, the principal is responsible for safeguarding the rights of the data subjects. The contractor shall inform the principal immediately if data subjects assert their rights against the contractor. The contractor shall immediately forward any enquiries from data subjects to the controller. The contractor shall not process any enquiries from data subjects without the instruction of the principal.
- 3.3. Before the commencement of data processing, and then on a regular basis, the principal must verify that the technical and organisational measures for data security implemented by the contractor are being complied with. The principal shall document the results of such verifications in an appropriate manner.

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3.4. The principal has the right at any time to issue the contractor with additional instructions regarding the type, scope and procedure for data processing. Instructions may be given

- in writing
- via e-mail
- by telephone.

The principal should immediately confirm verbal instructions to the contractor in writing (e.g. by e-mail) if verbal instructions are permitted in this agreement.

3.5. Rules regarding any potential compensation for additional expenditure arising as a result of the principal's additional instructions to the contractor remain unaffected.

3.6. The principal may nominate people who are authorised to give instructions. The contractor must be informed in a timely manner of those people authorised to give instructions on behalf of the principal.

If there are any changes to the people who are authorised to give instructions on behalf of the principal, the principal shall inform the contractor either in writing or in text form.

3.7. The principal shall inform the contractor immediately in the event of identifying any errors or irregularities in connection with the processing of personal data by the contractor.

3.8. If there is any obligation to provide information on third parties in accordance with Art. 33, 34 GDPR, the principal is responsible for complying with this obligation.

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4 Rights and obligations of the contractor

- 4.1. The contractor processes personal data solely within the limits of the agreements made and/or in compliance with any additional instructions that may have been communicated by the principal. The purpose, type and scope of data processing is based solely on this agreement and/or the principal's instructions. The contractor is forbidden from processing any data that does not comply with the above unless such processing has been approved in writing by the principal. The contractor undertakes to complete data processing on behalf of the principal only in member states of the European Union (EU) or the European Economic Area (EEA).
- 4.2. Files and documents containing personal data that is no longer required should only be destroyed after prior approval by the principal. Destruction should also be compliant with data protection requirements.
- 4.3. The contractor confirms that they have nominated an operational data protection officer in accordance with Art. 37 GDPR. The obligation to provide confirmation may be waived at the discretion of the principal if the contractor can provide evidence that they are not legally obliged to appoint a data protection officer and if the contractor can provide evidence of existing operational rules that ensure that the processing of personal data complies with legal provisions, the rules contained within this agreement and any other instructions issued by the principal.
- 4.4. Within the scope of the agreed processing of personal data, the contractor ensures the proper execution of all agreed measures.
- 4.5. The contractor is obliged to organise their business and operational procedures to ensure that the data processed on behalf of the principal is secure to the extent necessary and protected against unauthorised access by third parties. If the contractor needs to make any changes to the organisation of the contracted data processing that are relevant to data security, the contractor shall first agree these changes with the principal.
- 4.6. The contractor shall inform the principal immediately if they consider an instruction issued by the principal is in breach of any legal regulations. The contractor is authorised to suspend execution of the instruction concerned until it has been confirmed or amended by the principal.
- 4.7. The contractor is obliged to inform the principal immediately of any breach of data protection regulations or of contractual arrangements made and/or of instructions issued by the principal arising in the course of data processing by them or anyone else employed in such data processing. Furthermore, the contractor shall inform the principal immediately if a supervisory authority takes action against the contractor in accordance with Art. 58 GDPR and such action may also involve an inspection of the processing undertaken by the contractor on behalf of the principal.
- 4.8. If the contractor establishes, or if facts give rise to the belief, that the data being processed on behalf of the principal includes
 - particular types of personal data (Art. 9 GDPR) or
 - personal data subject to professional secrecy or
 - personal data referring to criminal activities or offences or the suspicion of criminal activities or offences (also according to Art. 10 GDPR) or
 - personal data relating to bank accounts or credit card accounts or
 - personal data that has been unlawfully transmitted or become available unlawfully in any other way to third parties,

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the contractor must inform the principal immediately and fully of the time, type and scope of the incident(s), either in writing or text form (fax/e-mail). The information provided must include a description of the nature of the unlawful acquisition of knowledge. The information must also include a description of any potential adverse consequences of the unlawful acquisition of knowledge. The contractor is also obliged to immediately disclose which measures the contractor has taken to avoid unlawful transmission and/or unauthorised access by third parties in future.

The contractor is aware that, in accordance with Art. 33 GDPR, there may be a reporting obligation for the principal to submit a report to the supervisory authorities within 72 hours of becoming aware of the issue. The contractor shall support the principal with the relevant reporting obligations.

- 4.9. The processing of data on behalf of the principal anywhere other than the contractor's or subcontractor's business premises is only permitted with the agreement of the principal in writing or text form. Processing of data on behalf of the principal in private homes is only permitted with the agreement of the principal in writing or text form in each individual case.
- 4.10. The contractor shall label the data processed on behalf of the principal in a suitable manner. If the data is processed for various purposes, the contractor shall label the data with the relevant purpose.
- 4.11. The contractor must assist the principal in creating the directory of processing tasks. The contractor must duly provide the principal with the necessary information, as appropriate.
- 4.12. The contractor must advise the principal of the names of the person/people authorised to receive instructions from the principal. The person authorised to receive information on behalf of the contractor is
 - Dr. Daniel Körner (Head of Software Development)
- 4.13. If any form of processing is likely to result in a high risk to the rights and freedoms of natural people, the principal must undertake an assessment of the consequences of the anticipated processing procedures for the protection of personal data. The contractor must assist with the implementation and duly inform the principal of any necessary information.
- 4.14. The contractor is obliged to assist the principal with the creation of a data protection impact assessment in accordance with Art. 35 GDPR and any prior consultation with the supervisory authorities in accordance with Art. 36 GDPR.

5 Monitoring authorities

- 5.1. The principal has the right, at any time and as far as necessary, to monitor compliance with the legal provisions for data protection and/or compliance with agreements made between the parties as part of this agreement and/or the contractor's compliance with the principal's instructions.
- 5.2. The contractor is obliged to provide information to the principal, insofar as this is required for completion of monitoring according to Para. 1.
- 5.3. The principal may request to inspect data processed by the contractor on behalf of the principal, as well as the data processing systems and programs used.
- 5.4. After prior notification in good time, the principal may, according to Para. 1, undertake monitoring on the contractor's business premises within the respective regular working hours. The principal shall ensure

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that monitoring is only undertaken to the extent necessary so that monitoring does not excessively disrupt the contractor's business operations.

- 5.5. In the event of measures against the principal by the supervisory authorities in accordance with Art. 58 GDPR, particularly with regard to information and monitoring obligations, the contractor is obliged to issue the necessary information to the principal and to allow the respective responsible supervisory authority to conduct an on-site inspection. The contractor must inform the principal of the relevant measures planned.

6 Subcontractual relationships

- 6.1. The contractor is only permitted to commission subcontractors with written agreement from the principal. The contractor shall specify all subcontractual relationships already existing at the time of concluding this agreement in "**Appendix 1**" to this agreement.
- 6.2. The contractor must select subcontractors carefully and, prior to commissioning them, must verify that they are able to comply with the agreements made between the principal and contractor. Prior to the contractual period in particular, and regularly during its term, the contractor must check that the subcontractor has taken the necessary technical and organisational measures for the protection of personal data in accordance with Art. 32 GDPR. The result of this check must be documented by the contractor and submitted to the principal on request. The contractor is obliged to ask the subcontractor to confirm that they have appointed an operational data protection officer in accordance with Art. 37 GDPR, unless this is not mandatory.
- 6.3. The contractor must ensure that the rules agreed within this agreement and any additional instructions from the principal also apply to subcontractors. The contractor must regularly monitor compliance with these obligations.
- 6.4. The contractor must conclude an order processing agreement with the subcontractor that complies with the provisions of Art. 28 GDPR. A copy of the order processing agreement must be submitted to the principal on request.
- 6.5. The contractor is particularly obliged, by means of contractual regulations, to ensure that the monitoring permissions (Section 5 of this agreement) of the principal and supervisory authorities also apply to the subcontractor, and that corresponding monitoring rights by the principal and supervisory authorities are agreed. It must also be stipulated in the agreement that the subcontractor is required to comply with these monitoring measures and any on-site inspections.
- 6.6. If subcontractors in a third country need to be involved, the contractor must ensure that an appropriate level of data protection is guaranteed by the respective subcontractor in accordance with Articles 44 ff. GDPR.

In countries outside the EEA region and with no existing adequacy resolution from the EU commission in particular, this could be achieved by means of an agreement based on the EU standard contractual clauses, existing binding corporate rules or a code of conduct.

When requested by the principal, the contractor shall provide evidence of the conclusion of the aforementioned agreements with their subcontractors.

- 6.7. Services used by the contractor with third parties purely as an ancillary service for the purposes of executing business activity must not be considered as subcontractual relationships according to paragraphs 1 to 5. These include, for example, cleaning services, telecommunication services only with no

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specific reference to services that the contractor provides for the principal, post and courier services, transport services and surveillance services. Nevertheless, even when it comes to additional services provided by third parties, the contractor is obliged to ensure that appropriate arrangements are made and technical and organisational measures are taken to guarantee the protection of personal data. Maintenance and inspection services constitute subcontractual relationships requiring approval if the maintenance and inspection work concerns IT systems that are also used in connection with the provision of services for the principal. The parties agree that the aforementioned maintenance and inspection services constitute "order processing" according to Art. 28 GDPR.

7 Contractor's data protection officer

As its expert data protection officer, the contractor has appointed:

Mr Sven Lenz

German Data Protection Office – Datenschutzkanzlei Lenz GmbH & Co. KG

Bahnhofstraße 50

87435 Kempten

Germany

E-mail: dsb@heine.com

Web: www.deutsche-datenschutzkanzlei.de

The certificate of specialist knowledge regarding the qualification of the data protection officer is appended to this agreement.

Any change in data protection officer must be communicated immediately to the controller. The current certificate of specialist knowledge must be provided to the controller at their request.

8 Obligation of confidentiality

- 8.1 In processing data for the principal, the contractor is obliged to maintain the confidentiality of data received in connection with the order and/or of which they become aware. The contractor is obliged to comply with the same rules regarding the protection of secrecy incumbent on the principal. The principal is obliged to inform the contractor of any particular rules regarding the protection of secrecy.
- 8.2 The contractor ensures that they are aware of the respective and applicable data protection regulations and that they are familiar with their application. Furthermore, the contractor ensures that any of their employees working with the data are aware of the relevant data protection provisions and that they are obliged to maintain their confidentiality.
- 8.3 The contractor is aware that the principal, as a doctor, is subject to a particular duty of confidentiality in accordance with § 203 of the German Criminal Code. The contractor shall provide all employees involved in the provision of services in connection with the principal's instruction with a written obligation to treat as confidential all data belonging to the principal, particularly personal data processed for the principal. The contractor shall also subject the employees working with specific personal data (Art. 9 GDPR) to a separate duty of confidentiality in accordance with § 203 of the German Criminal Code. Evidence of this employee obligation must be provided to the principal on request.

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9 "Home office" rule

Home office working, is a flexible form of working where employees complete all or part of their work in their own private environment.

- 9.1 The contractor may permit their employees commissioned with processing personal data on behalf of the principal to process that personal data in their own private home ("home office").
- 9.2 The contractor must ensure that compliance with contractually agreed technical and organisational measures is also guaranteed in the "home office" of the contractor's employees. Deviations from individual contractually agreed technical and organisational measures must first be approved in writing by the principal.
- 9.3 The contractor shall, in particular, ensure that where personal data is processed in the "home office", storage locations are configured to ensure that it is impossible for IT system data used in the "home office" to be stored locally. If this cannot be achieved, the contractor must ensure that local storage is encrypted and that no-one else in the household can obtain access to the data.
- 9.4 The contractor is obliged to ensure that it is possible for the principal to conduct effective monitoring of personal data being processed on their behalf in the "home office". In the process, appropriate consideration must be given to the personal rights of employees and other persons living in the respective household.

10 Safeguarding the rights of data subjects

- 10.1 The principal is solely responsible for safeguarding the rights of the data subjects.
- 10.2 Where the contractor and the principal are required to work together to safeguard the rights of data subjects – particularly regarding information, rectification, blocking or deletion – the contractor shall take the necessary measures as instructed by the principal.
- 10.3 Rules regarding any potential compensation for additional expenditure arising for the contractor as a result of co-operative efforts in connection with data subjects exercising their rights towards the principal remain unaffected.

11 Confidentiality obligations

- 11.1 Both parties are obliged to treat any information received in connection with the execution of this agreement as confidential for an indefinite period and to only use this information for the execution of this agreement. Neither party is authorised to use any of this information, either in full or in part, for anything other than the aforementioned purposes or to make this information accessible to third parties.
- 11.2 The aforementioned obligation does not apply to information that either party may have verifiably received from a third party, for which no duty of secrecy applies, or which is already in the public domain.

12 Compensation

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The contractor's compensation shall be agreed separately.

13 Technical and organisational measures for data security

- 13.1 The contractor gives their undertaking to the principal to comply with the technical and organisational measures required for compliance with the applicable data protection regulations.
- 13.2 The status of the technical and organisational measures at the time of concluding this agreement is included as "**Appendix 2**" to this agreement. The parties agree that amendments of technical and organisational measures may be required to align these measures with changes in technical and legal circumstances. The contractor shall ensure prior agreement with the principal for key amendments that may compromise the integrity, confidentiality or availability of personal data. Measures that only involve minor technical or organisational amendments and that do not have a negative impact on the integrity, confidentiality and availability of personal data may be implemented by the contractor without agreement with the principal. The principal may, at any time, request a current statement of the technical and organisational measures taken by the contractor.
- 13.3 The contractor shall regularly monitor the technical and organisational measures being taken and check their effectiveness as necessary. In the event that an optimisation and/or change is required, the contractor shall inform the principal.
- 13.4 The contractor shall provide the principal, in writing and as appropriate, with details of the technical and organisational measures taken in accordance with Art. 32 GDPR to ensure compliance with Art. 32 GDPR and the level of protection set out in this agreement. Provided that the parties have not made a separate agreement that the technical and organisational measures detailed in "**Appendix 2**" shall be replaced by the newly documented technical and organisational measures for data security in accordance with this paragraph, the measures detailed in "Appendix 2" shall remain an integral part of this agreement and must be fulfilled by the contractor accordingly.

In addition to the technical and organisational measures detailed in "**Appendix 2**", the contractor shall also implement the technical and organisational measures set out below to protect the principal's most sensitive patient data in HEINE DERManager:

- Creation of user profiles with limited user rights for the IT systems used
- Authentication with username and password or (preferably) with cryptographic key
- Encryption of all connections with IT systems
- Dispense with mobile data carriers
- Encryption of data carriers in laptops/notebooks
- Protect connections via firewalls
- Creation of an authorisation concept
- Management of rights by system administrators
- Limit the number of administrators to the bare minimum
- Password guidelines
- Logging of access to applications, particularly for entering, amending and deleting data
- Strict client separation by means of separate virtual machines with separate database
- Separation of production and test system
- The principal shall not pseudonymise the data. The specific assignment of patient data is essential for the software to function.
- All connections to the IT systems are encrypted (transport encryption). Data at rest, such as backup files, is not normally encrypted.

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- The decision to encrypt as an option for protecting personal data rests with the principal. If the principal opts for data encryption, the contractor can also offer to store the key for any potential data recovery. If this is not done and the contractor loses the key, all data encrypted with that key is irretrievably lost.
- The transfer of data from the system to the user is restricted by the rules for accessing the software
- The transfer is encrypted
- During transfer, algorithms are used to correct errors
- System logins are recorded
- Traceability of data entry, amendment and deletion through individual usernames (not user groups)
- Assignment of rights for data entry, amendment and deletion based on an authorisation concept
- Careful selection of the contractor (particularly with regard to data security)
- Obligation of contractor's employees to maintain confidentiality
- Contractor has appointed data protection officer(s)
- Continuous review of the contractor and their activities

14 Duration of contract

- 14.1 The agreement begins with the order for work and/or services in accordance with section 2.1 and is concluded for an indefinite period. The duration of the agreement is linked to the duration of the subscription.
- 14.2 The agreement can be terminated at any time with notice to the end of the current subscription. The duration of a subscription is one month. The agreement extends for another month if no termination request is made.
- 14.3 The principal may terminate the agreement at any time without notice in the event of a serious infringement by the contractor of the applicable data protection regulations, or of the obligations of this agreement, if the contractor cannot or will not fulfil an instruction issued by the principal, or, contrary to the terms of the agreement, if the contractor denies access to the principal or the responsible supervisory authority.

15 Cessation

- 15.1 Following cessation of the agreement, the contractor must deliver to the principal all documents, data and processing or usage results compiled in connection with the contractual relationship. The contractor's data carriers must then be physically deleted; deletion must take place within a grace period of one month. This also includes any data backups made by the contractor. The deletion must be appropriately documented. Test and waste material must be destroyed or physically deleted immediately.
- 15.2 The principal has the right to check that the contractor has returned and deleted the data in full and in compliance with the contract. This may also be achieved by means of a visual inspection of the data-processing facilities on the contractor's business premises. The principal should provide an appropriate period of notice for the on-site inspection.

16 Right of retention

The parties agree that the contractor's right of retention in relation to the data processed and the associated data carriers, in accordance with § 273 BGB (German Civil Code), shall not apply.

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17 Final provisions

- 17.1 If the principal's property with the contractor is at risk as a result of third-party measures (e.g. attachment or sequestration), an insolvency procedure or other event, the contractor must inform the principal immediately. The contractor shall immediately inform creditors that data is being processed on behalf of a third party.
- 17.2 Subsidiary agreements must be made in writing.
- 17.3 If a condition of this agreement should become invalid or inapplicable, this will in no way affect the validity of the remaining conditions of this agreement.

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Appendix 1: Subcontractor

SaSG GmbH & Co. KG
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Fax: +49 (0) 82 06 - 5 27 90 - 29

E-mail: [info\(at\)sasg.de](mailto:info(at)sasg.de)
Web: www.sasg.de

Commercial register (HRA) 18415

Personally liable partner:
SaSG Verwaltungsgesellschaft mbH, commercial register (HRB) 29326

Managing director authorised to represent the company: Peter Heidenreich

Appendix 2: Contractor's technical and organisational measures

Appendix 3: Subcontractor's technical and organisational measures