



Framework Procurement Agreement

between

**Carl Zeiss Meditec AG
Göschwitzer Strasse 51-52
07745 Jena**

- hereinafter referred to as the “Client” -

and

**Company name
Street address
City and zip code
Country**

- hereinafter referred to as the “Contractor”

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1. Contractual Object, Beneficiaries, Contractual Content

- 1.1. The Contractor undertakes to supply the Client with the objects or services described in further detail in the respective quantity contracts, orders, pricelists, specifications or consignment stock agreements (hereinafter referred to as “products”) in accordance with this Contract. The subject of the Contract are the agreed regulations for all deliveries of products from the Contractor’s supply range to the Client. The Client uses the products delivered worldwide in medical devices.
- 1.2. The Contractor also assumes the obligation in accordance with clause 1.1 towards Carl Zeiss Meditec AG and all associated companies in accordance with Section 15 Stock Corporation Act. “Client” therefore refers to all companies who are entitled to request the delivery of products from the Contractor in reference to this Contract.
- 1.3. Insofar as nothing to the contrary is agreed upon in writing, the provisions of this Contract shall apply exclusively to the supply of these “products”. Contradictory sales, purchasing, contractual or business terms and conditions of the Contractor shall also not apply if the Client does not explicitly oppose them in each individual case, in particular by accepting products ordered without contradiction. In this respect, the Contractor irrevocably waives the right to assert provisions of its general terms of sale or business terms and conditions in business with the Client.

2. Contractor Obligations

- 2.1. The Contractor shall supply the Client with its products based on each separate order by the Client with its products in accordance with this framework agreement.
- 2.2. The Contractor must not implement any changes in the production process for products that are the object of this agreement without informing the Client twelve (12) months prior to implementation.
- 2.3. The Contractor shall enclose a delivery note with each delivery, which contains the order number, parts number, a description of the goods ordered as well as the quantity of contents. Insofar as the products require batch numbers or serial numbers or are subject to a limited shelf life date, this information must be stated on the delivery note accordingly.
- 2.4. The Contractor is obliged to inform the Client eighteen (18) months in advance if the Contractor foresees the discontinuation of one of the contractual products. In this case, the Client shall be entitled to place an “end-of-life” order that comprises at least one year’s requirement after the discontinuation of production. The Contractor undertakes to fulfill this

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“end-of-life” order.

- 2.5. During the ongoing supply with a product and up to 6 months beyond the last delivery, the Contractor must monitor the availability status of the components the Contractor acquires from sub-suppliers for the product, even if its requirements for ongoing or already expired orders are already fully covered. In the event of limited availability, the Contractor must inform the Client immediately.
- 2.6. The Contractor must inform the Client of any incident involving any OEM product the Contractor has produced, which has caused or could cause a fatality or which presents a serious threat to the life, limb or health of a customer or patient, within forty-eight (48) hours of becoming aware of such an incident. The Contractor shall take all the necessary steps to detect and investigate such incidents. Should the Contractor use retailers or third parties for the marketing of medical devices, this shall not impact the obligations of the Contractor in accordance with this Clause 2.56. Furthermore, the Contractor shall be responsible for effecting all measures to fulfill the aforementioned obligations towards the Client.
- 2.7. The Contractor shall ensure its products’ competitiveness over the term of this Contract.
- 2.8. The Contractor shall collect all complaints (e.g. all oral or written notifications of dissatisfaction regarding OEM products manufactured by the Contractor in terms of safety, performance, identity, quality, reliability and effectiveness) and shall pass these on to the Client promptly and on a regular basis.
- 2.9. The Contractor must grant the Client full access to the product drawings by no later than the day of the entry into force of this Contract. The Client may use, copy or amend the drawings for any purpose at its own discretion.
- 2.10. In the case of OEM products, the Contractor shall demonstrate the equivalence of products in writing.

3. Orders (planning)

- 3.1. Should the Client desire the supply of products, the Client shall send a corresponding written order to the Contractor. The Client shall define specifications, quantities and delivery deadlines in such orders. The order may be placed in writing, via fax or via electronic data transfer. Orders via electronic means are also valid without signature.
- 3.2. The Contractor shall confirm the order in writing or in electronic form immediately upon receipt, whereby points in which the confirmation deviates from the order are clearly highlighted. An agreement on these

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points must be achieved in writing as quickly as possible. An order is binding as soon as the Client has received the order confirmation without deviations from the Contractor or a written or electronic agreement has been reached regarding deviating points.

A confirmation can also be provided by means of the complete and on-time delivery of the contractual objects ordered. In this case, the Contractor shall also remain obliged to provide an order confirmation to the Client immediately upon receipt of the order.

- 3.3. The Client may revoke the order free of charge if the Contractor has not confirmed the order unchanged within 2 weeks of receipt or if no agreement about outstanding points has been reached in writing.
- 3.4. The Client is entitled to withdraw orders and to reduce or increase delivery quantities. Insofar as changes would cause an increase in costs or the deadline being exceeded, the Contractor undertakes to report this immediately. Insofar as changes have an impact on prices, the Contractor shall justify this in a clear way. Each amendment only applies as having been agreed on a binding basis if an additional written agreement between the parties has been reached concerning the effects, in particular on prices as well as on the deadlines. The details are governed in the individual quantity contracts.
- 3.5. The Client is not obliged to place orders.
- 3.6. The Client shall only pay for services that are provided on the basis of an order or a written approval by the purchasing department. For services for which no order or written approval exists, there is no entitlement to remuneration or expenses etc.

4. Prices, Payment Terms

- 4.1. The prices are fixed prices. They include all expenses in connection with the products to be supplied by the Contractor. The prices are net of statutory value added tax. The delivery will be made to the Client's premises, including packaging in accordance with Incoterms 2010: DAP. Insofar as transport takes place as the cost of the Client, the Client's routing order must be taken into account.
- 4.2. Invoices are to be submitted to the Client to the invoice address stated on the order, in a single copy stating the order number.
- 4.3. The payment is made by the Client within sixty (60) days of receipt of the products and the invoice without deduction. Payment has been made by the Client by the deadline if the Client's bank has received the transfer

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order or the check has been sent by the payment deadline.

- 4.4. Payments do not imply any acknowledgment of the products as being compliant with the Contract. In the case of defect or incomplete products, the Client shall be entitled, without prejudice to its other rights, to withhold payments for all claims arising from the business relationship with the Contractor to an appropriate extent until the proper fulfillment of the order.

5. Processing and Delivery

- 5.1. Subcontracting of the total order may only take place with the prior written or electronic approval of the Client. Any subcontractors of the Contractor shall in particular be bound by the confidentiality obligations (Clause 198).
- 5.2. Part deliveries shall require the prior written consent of the Client.
- 5.3. All deliveries must be carried out in the quantities that were ordered and confirmed. If a Contractor foresees that it shall not be able to fulfill a delivery at all or not completely, the Contractor must inform the Client immediately via fax or via email. At the request of the Client, the Contractor must deliver the quantities available. The acceptance of part deliveries by the Client does not imply recognition of a delivery as complete or on time. In the event of the threat of a delay or an actual delay to the complete delivery, the Contractor shall supply the products that are available as quickly as possible, via courier where necessary. The additional costs incurred as a result shall be borne by the Contractor. Clause 6 of this Contract remains unaffected.
- 5.4. Should the Contractor delivery more products than those ordered, the Client shall be entitled to retain these products and so to reduce the delivery volume of a future order not yet delivered or to store the products at the cost of the Contractor or return the excess products to the Contractor at its expense.
- 5.5. Changes to specifications, production methods, production sites or suppliers must be reported to the Client in writing promptly before their planned implementation. The change in the manufacturer of any identical material is regarded as a change to specifications. The delivery of changed contractual objects in any case requires the explicit prior written consent of the Client, potentially as part of another initial sample approval.
- 5.6. A certificate of analysis (COA) and a certificate of conformity (COC) must be enclosed with each delivery (each batch).
- 5.7. For devices, a technical description and instructions for use and

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maintenance must also be delivered free of charge.

- 5.8. In the case of software products, the delivery obligation is only fulfilled once the complete system documentation and/or the user documentation has been handed over and mutual acceptance on the Client's system (in accordance with the user requirements specification) has been performed. In the case of programs created specifically for the Client, the program must also be supplied in source code format. In the case of programs that were developed for the Client, the Contractor immediately transfers to the Client an irrevocable, exclusive right of use, unlimited in terms of time, location and content, to these programs. The Client's right of use takes effect upon payment of the order and is otherwise granted free of charge. Requirements going beyond this general framework are specified in separate appendices.
- 5.9. For the duration of ten (10) years after the time of the discontinuation of series products, the Contractor shall provide replacement parts or subcomponents and/or servicing for the products, provided that nothing to the contrary is agreed upon in individual cases.
- 5.10. Should the Contractor foresee the discontinuation of the manufacture of replacement parts or subcomponents or products, the Contractor shall inform the Client in writing eighteen (18) months in advance and provide the Client with the option to sufficiently cover its needs with the delivery lots to be agreed upon. Quantities, batch sizes and acceptance periods for subcomponents are agreed upon separately between the parties.
- 5.11. For the delivery of replacement parts and subcomponents, the provisions of this Contract shall apply accordingly, provided that no separate written agreement has been made.

 Should the Client wish to pay for the repair of products or subcomponents, the Client shall send the subcomponents or products with a repair/order to the Contractor and requests a quote for costs. The costs specified in the quote are binding. The Contractor's quote shall be reviewed by the Client and approved where appropriate. Following approval of the quote by the Client, the repair or maintenance must be carried out by the Contractor. The repair or maintenance time following approval of the quote totals 10 working days, provided that nothing to the contrary has been agreed upon between the parties. The Contractor must inform the Client in good time if the costs may possibly be exceeded. In the event of the costs specified in the quote being exceeded, the Client shall be entitled to withdraw from the order free of charge.
- 5.12. At the request of the Client, the Contractor must take back or dispose of packaging material delivered with the products at its own cost. Should the Contractor not comply with this obligation within an appropriate

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period, the Client may have the packaging material disposed of at the expense of the Client. As part of recurring deliveries, the return may also take place at one of the next deliveries, in consultation with the Client.

6. Deadlines and Consequences of Missed Deadlines

- 6.1. The deadlines agreed for the delivery of products are binding. In the event of an agreed deadline being exceeded, the Contractor shall be in default. If delays are expected or occur, the Contractor must inform the Client immediately.
- 6.2. Should the Contractor shall be in default, the Client shall be entitled, without prejudice to its other rights, to charge a delay fee from the second day following the agreed delivery date amounting to 0.5 % of the entire order value per calendar day of the delay, but in any case a minimum fee of € 250. The maximum amount of the delay fee is € 5,000 or 10 % of the total order volume, whichever is the highest. The payment is due from the second day following the agreed delivery deadline, unless there is a case of force majeure or the Contractor demonstrates that less damage has been suffered. The Client reserves the right to demonstrate higher expenses.
- 6.3. Should the Contractor also not deliver outside of an appropriate grace period set by the Client, the Client shall be entitled, without warning, to reject fulfillment and either to withdraw from the contract/the order in question and/or demand compensation for damages due to non-fulfillment.
- 6.4. The Contractor is informed that the Client is subject to contractual penalty provisions towards its own customers. Should a delay on the part of the Contractor lead to the Client having to pay contractual penalties to its customers, the Contractor shall reimburse the Client for these penalties as compensation for loss suffered.

If, in spite of a previous warning letter from the Client, the Contractor once again delivers defective Products or delivers late, the Client is entitled to withdraw from the SAP contracts and from open purchase orders without further ado, including in respect of such Products and services which the Contractor is still obliged to supply to the Client in the future by reason of other contractual relationships.

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7. Environment, Quality, Occupational Protection, Conflict Minerals

7.1. Environmental management and product safety

7.1.1. The Contractor assures and, upon the request of the Client, shall also provide written evidence for the product:

- That the products to be supplied meet legal requirements,
- That certain ingredients are not included in the product (banned and avoidance list, a list of the banned substances can be found on the website at www.zeiss.de/meditec at Rechtshinweise - AGB or: www.zeiss.com/meditec at Legal Information - Terms and Conditions)
- Of which substances are included or could be emitted in which relative or absolute quantitative volume.

The health and safety of employees are fundamental values of the Client's corporate policy.

The Client feels particularly committed to being responsible and environmentally friendly. It expects the same of the Contractor.

The Contractor's products must comply with all applicable statutory provisions, in particular safety, occupational safety, accident prevention and environmental protection provisions. The Contractor shall exempt the Client from all third-party claims that refer to a violation of statutory regulations by the Contractor.

When supplying the Client with hazardous materials, the Contractor must enclose safety data sheets unrequested and free of charge. In the case of the delivery of machines and systems, the necessary declarations of conformity (CE marks) are also to be supplied free of charge.

Necessary protective gear or manufacturer instructions are also to be provided by the Contractor free of charge.

The Contractor has implemented suitable measures to ensure that the Contractor's products meet the requirements in Section 1502 of the Dodd-Frank Act regarding the use of so-called conflict materials (e.g. tantalum, wolframite, coltan or gold).

7.1.2. The Contractor shall explicitly refer to its product responsibility in accordance with the directives, laws and legal prescriptions:

- RoHS directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (2011/65/EU)

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- Restriction on Marketing and Use of Dangerous Substances and Preparations Directive (76/769/EEC)
- Regulation no. 1907/2006/EC concerning the Registration, Evaluation, Authorization and Restriction of Chemicals
- Directive on batteries and accumulators and waste batteries and accumulators (2006/66/EC) and the German Battery act
- German Device and Product Safety Act (GPSG) and associated regulations
- German Recycling and Waste Management Act (KrWAbfG) and associated regulations, including the German Packaging Ordinance (VerpackV) and the German Battery Ordinance (BattV)
- German law governing the marketing, return and environmentally-friendly disposal of electrical and electronic devices (ElektroG)
- German Water Resources Act (WHG) and associated regulations
- German Federal Emissions Act (BImSchG) and associated regulations, including the German Ordinance on Hazardous Substances (GefStoffV) and German Prohibition of Chemicals Ordinance (ChemVerbotsV).

7.1.3. No ozone-depleting substances (e.g. CFCs, carbon tetrachloride, 1,1,1-trichloroethane etc.) may be used in the manufacture of products. The provisions of the German CFC Prohibition Ordinance must be observed by the Contractor.

7.1.4. The Contractor is obliged to regularly catch up on newly approved or amendments to existing German and European environmental laws. The contractor must consistently ensure that the goods delivered correspond to the statutory requirements valid at the time of delivery. In particular, the Contractor shall be obliged to supply RoHS-compliant products. Should the Contractor detect that in his opinion amended statutory requirements make an adjustment to agreed specifications necessary, the Contractor must inform the Client of this in writing in advance and provide the Client the opportunity to provide an opinion on this within an appropriate period. In such a case, the Client and the Contractor shall consent to the further course of action in good faith.

7.2. Quality management and product quality

7.2.1. The Contractor undertakes to bear sole responsibility for the planning, organization and implementation of quality assurance measures in such a way that comprehensive control and monitoring is guaranteed and that the quality and safety requirements for the products are observed. The Contractor shall provide its services in application of a quality management system, which meets the requirements of EN ISO 9001 et

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seqq., ISO 13485, ISO 14001, ISO 50001 and OHAS 18001, and shall continuously develop this system in line with state-of-the-art technology.

The conclusion of a quality assurance agreement is desired to demonstrate the Contractor's quality capabilities.

The Contractor undertakes to bear sole responsibility for the implementation of quality assurance measures in line with the Contractor's obligations as described in **Appendix 1**.

7.2.2. The Client may – with prior notice – perform regular audits at the Contractor's premises. Upon request, the Contractor undertakes to provide the Client with data about the stability of its processes.

7.2.3. The Contractor has been informed that it, as a supplier of medical devices, bears particular responsibility and also may potentially be subject to direct monitoring by the authorities or a notified body. Audits by these bodies may take place without being announced. The Contractor must facilitate the performance of these audits by the authorities or the notified body.

7.2.4. The Contractor undertakes to provide the Client with free-of-charge advice regarding relevant questions that concern the quality of the product, in order to achieve a mutual understanding of quality.

7.3. Occupational safety management and occupational safety

The Contractor bears sole responsibility for observing the German Act on the Implementation of Measures of Occupational Safety and Health to Encourage Improvements in the German Safety and Health Protection of Workers at Work (ArbSchG) as well as the Accident Prevention Regulations. In accordance with these regulations, the necessary safety equipment or manufacturer instructions are also to be provided free of charge, in order to guarantee the safe and secure operation of the products in accordance with the German Industrial Safety Regulation (BetrSichV).

8. Import and Export Regulations, Customs

8.1. In the case of deliveries and services that come from an EU member state outside of Germany, the Contractor must provide its EU VAT identification number. If the Contractor is headquartered in a member state of the European Union, deliveries to the Client must be delivered duty paid, except where otherwise stipulated by other agreements between the parties.

8.2. The Contractor is obliged always to observe the foreign trade regulations (in particular export controls and customs regulations) that apply in the supplier country or at its headquarters and – where applicable – the

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regulations of the United States of America. In all of the sales documents enclosed with the deliveries (delivery note, invoice etc.), the Contractor must indicate all services requiring export licenses or subject to US (re-)export provisions with corresponding classification (export list categories, number of European dual use lists or Export Control Classification Number), as well as specify the applicable harmonized system number (HS code) and the country of origin. The Contractor undertakes to provide at its own expense all declarations and information required to be provided in accordance with (EC) Regulation no. 1207/2001, to allow audits by the customs authorities and to procure official confirmations required.

- 8.3. If the services provided are technology within the meaning of technical knowledge, which is subject to US export control regulations (EAR, ITAR), the European Dual Use Regulation or the German export list, the Contractor is obliged to inform the Client of this in writing.

9. Insurance

- 9.1. The Contractor undertakes to take out appropriate insurance policies for the materials provided by the Client. Here, it must be ensured that the insurance policies also cover third-party property.
- 9.2. The Contractor also undertakes to take out appropriate product liability insurance.
- 9.3. The Client must be permitted to inspect the insurance documents or be provided evidence thereof upon request. Should the Contractor not observe its insurance obligations despite the Client's request, the Client shall be entitled to the extraordinary termination of the Contract for good cause.

10. Transfer of Risk, Acceptance, Property Rights

- 10.1. Regardless of the agreed pricing, the risk transfers to the Client
- for delivery without set-up or assembly, upon receipt at the delivery address specified by the Client,
 - for delivery with set-up or assembly, with the successful conclusion of acceptance.

The commissioning or usage of the product(s) does not replace the Client's declaration of acceptance.

- 10.2. Upon delivery of the products subject to retention of property, the Contractor agrees to resale as part of proper business operations. The Client acquires the property at the latest upon the payment of the full

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remuneration.

11. Duties of Inspection and Complaint

- 11.1. The client will report obvious defects of the products without delay. In the case of defects that appear to the Client within four (4) weeks of delivery, the Contractor waives its right to object to the belated notice of defect.
- 11.2. The Contractor must conduct and document a final inspection in line with the agreed specifications and – where required by the Client – to be demonstrated in a test log (e.g. Producer Inspection Certificate M in line with DIN 55350). The Client reserves the right to inspect individual characteristics upon receipt of goods.
- 11.3. If the Client returns defect goods, the Client shall be entitled to charge the invoice amount back to the Contractor plus the costs of return delivery and a flat-rate for expenses amounting to € 250.00. The Client reserves the right to demonstrate higher expenses.

12. Warranty for Defects of Quality and Legal Defects

- 12.1. The Contractor warrants that the contractual object is free from defects. Defective products must be replaced immediately by defect-free products or defective services must be repeated flawlessly. In the event of development, construction or design defects, the Client shall be entitled to assert the rights set out in Clause 12.4 immediately.
- 12.2. Rectification of defect products requires the written consent of the Client. During the time that the product is not in the custody of the Client, the risk is borne by the Contractor. Rectified products must be clearly separated from series deliveries and clearly identified as rectified or repaired products.
- 12.3. In urgent cases (in particular in the event of operational safety being threatened or to avoid exceptionally high damage), to rectify slight defects as well in the event of the Contractor being behind schedule with the rectification of a defect, the Client shall be entitled, following prior information, to rectify the defect and any ensuing damage at the expense of the Contractor or arrange its rectification by a third party. This also applies if the Contractor delivers or provides a service late or and the Client must rectify defects immediately as a result in order to avoid being in default of delivery itself.
- 12.4. Should the Contractor also not rectify the defect within a grace period set by the Client, the Client shall be entitled to request replacement delivery,

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a change or a reduction at its discretion.

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- 12.5. The products must be exempt from third-party rights. In the case of the delivery of data processing programs, the Contractor shall be liable for ensuring that it possesses all the necessary rights, in particular intellectual property rights, to share the programs.
- 12.6. The warranty period for quality defects shall be thirty-six (36) months from the transfer of risk in accordance with Clause 10.1. The duration of the guarantee period is limited to the period that starts with the sending of the notice of defects by the Client and ends with the receipt of the defect-free product. For rectified or replaced products, the period referred to in (1) begins again upon the receipt of the defect-free product.
- 12.7. The Client's statutory requirements remain otherwise unaffected.
- 12.8. Should the Client's order be based on specifications for the products to be delivered agreed upon between the parties, the Contractor undertakes a guarantee that the composition of the products also meets these specifications.

13. Serial Defects

- 13.1. Should similar defects occur during the warranty period specified in Clause 12.6 or within a period of five (5) years after its expiry in more than 2 % of the products ("serial defects"), then all products delivered by the Contractor to the Client or directly to customers of the Client within the period specified shall be regarded as also demonstrating this defect.
- 13.2. The parties shall inform each other immediately of the occurrence of serial defects. The Contractor shall then immediately take all suitable measures to rectify the defects. In this case, the Contractor shall bear all costs associated with the performance of error rectification, in particular:
 - a) The costs for rectification or replacement delivery of the defect products, including compensation for manufacturing and processing costs incurred without avail.
 - b) The costs for the removal of defect products and installation of rectified or newly delivered products,

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- c) The costs for searches, e.g. inspections, tests, reports etc. carried out to determine the error,
- d) The costs for the inspections, tests etc. that are performed after error rectification, e.g. at the request of the Client's customers in connection with the acceptance of defect rectification,
- e) Travel and accommodation costs spent by the Client, including food and lodging costs to be reimbursed resulting from business or employment obligations.
- f) The costs and risk of returning defect products,
- g) The costs of any product recalls that may become necessary at the Client's discretion.

14. Product Liability

- 14.1. Should product defects lead to risks to life and limb or other damage, including third-party financial losses, the Client shall be entitled to take all measures at the cost of the Contractor, such as product recalls, to which the Client is obliged or which are necessary for other reasons in order to protect third parties from damage. The Client shall inform the Contractor if cases such as those in Clause 14.11 arise and keep the Contractor informed of the action it intends to take. The Contractor shall cooperate in a spirit of trust with the Client in order to eliminate risks associated with the defective products in as cost-effective a way and quickly as possible.
- 14.2. The parties undertake to exchange information about potential risks of damage and damage that has already occurred immediately. In the event of measures to avoid risks, the parties undertake to cooperate to ensure a seamless process.
- 14.3. In accordance with the Product Liability Act, the Contractor is regarded as the manufacturer of the product to be delivered.
- 14.4. The Contractor undertakes to exempt the Client from all claims that are raised against the Client as a result of a product defect in line with the German Product Liability Act or the product liability laws of the EU member states or a third state, if and insofar as the causes of damage arose in the manufacture and/or other area of responsibility of the

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This also applies to direct claims against the Client as well as for third-party recourse claims that satisfy the compensation claims of the damaged party.

- 14.5. In the event that third parties assert claims against the Client regarding goods acquired from the Contractor, the Client undertakes to inform the Contractor of this in good time and to make the corresponding documents available to Contractor.

The Contractor must then declare within ten (10) working days whether it will defend the claims asserted against the Client and the Client should reject said claims, or whether the Client should acknowledge the claims.

- 14.6. Should the Client issue a recall at the request of the Contractor or for any other reasonable cause, the Contractor shall bear the costs of the recall.

15. Emergency Production

- 15.1. The Client shall have the free-of-charge right to manufacture and market or arrange the manufacturing of products using the technical information and documents, including software programs and valid copyrights of the Contractor, used by the Contractor for their production and inspection. The Client shall avail of this right only if the Contractor discontinues production of the products or, for whatever reason, the Contractor has not completely fulfilled its delivery obligations for longer than two (2) months.

- 15.2. To ensure the right to emergency production in accordance with Clause 14.1, the Contractor shall immediately give the Client one (1) copy of each of the technical documents and software programs (in source and object code) it has used for the manufacture/inspection of the products in a sealed envelope ("escrow copy"). The Client shall also receive a list of the documents and programs handed over in a sealed envelope. The escrow copy must always be kept up to date via subsequent delivery of the revised documents and programs. The Client also receives the list revised accordingly.

- 15.3. The Client will use the escrow copies exclusively for the right of emergency production and will only break the seal for this purpose. The Contractor shall be entitled to verify the Client's observance of the provisions of this Clause at any time during the Client's normal business hours. The emergency production right also applies with regard to replacement and spare parts. It ends upon the Client's ability to delivery being restored and maintained for at least two (2) months.

- 15.4. The Client may request that the Contractor grants the ownership, in a

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legally binding way, of special production tools, which the Contractor uses for the manufacture and/or inspection of products for delivery to the Client (e.g. special tools, special equipment and gear) to the Client to ensure the observance of the emergency production right (“security ownership”). The objects subject to the security ownership are identified immediately in a way to be agreed upon the commencement of the Contract, e.g. by attaching special stickers.

- 15.5. In the event of emergency production by third parties, they shall promptly be committed to confidentiality obligations in accordance with Clause 198.

16. Provision of Material

- 16.1. Material provided by the Client remains the property of the Client and is stored separately by the Contractor from other items free of charge and with the care of a prudent businessman and must be labeled as the property of the Client. It may be used for the performance of the order only.
- 16.2. Should the Contractor process or reorganize the materials provided, it performs this activity for the Client. The Client shall immediately become the owner of the new items created as a result. Should the materials provided only make up part of the new items, the Client shall have co-ownership of the new items at the value that corresponds to that of the material contained therein.

17. Force Majeure

- 17.1. Neither party shall be liable for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party’s reasonable control, including without limitation Acts of God, fire, flood, earthquake or other natural forces, war, civil unrest, actions or decrees of governmental bodies, freight embargoes, worldwide shortage of raw materials or equipment, or labor disputes (a “Force Majeure Event”). Such excuse from liability shall be effective only to the extent and duration of the Force Majeure Event and provided that the affected party has not caused such Force Majeure Event to occur. Notice of a Force Majeure Event must be given to the other party within seven (7) days after its occurrence. All shipment dates under this Agreement that have been affected by a Force Majeure Event shall be tolled for the duration of such Force Majeure Event. If the Force Majeure Event continues for more than ninety (90) days, the party whose performance is not affected by the Force Majeure Event shall have the right, effective immediately upon written notice, to cancel any or all outstanding

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purchase orders and/or terminate this Agreement

18. Intellectual Property, Technical Documents, Tools, Means of Production

- 18.1. The products produced in accordance with the Client’s specifications are manufactured exclusively for the Client and may not be manufactured for the Contractor itself or for third parties or be marketed under the brand name or other label of the Client or a third party. All the other rights to the products shall be retained exclusively by the Client.
- 18.2. The technical documents, tools, worksheets, means of production etc. provided by the Client shall remain the property of the Client. All copyrights remain those of the Client. All documents, including all copies made, shall be returned to the Client unsolicited after completing the order, but at the latest at the termination of the contract. The Contractor shall have no right of retention. This shall exclude working copies. These working copies, especially documents that are used to demonstrate that the work has been performed correctly, must be stored in a place inaccessible to third parties as specified by the Client or in line with statutory deadlines.
- 18.3. Should the Contractor create the objects specified in Clause 18.2 for the Client at the Client’s expense, Clause 18.2 shall apply accordingly, whereby upon the creation of the objects, the Client shall become co-owner of the objects in accordance with its proportion of the production costs. The Contractor shall store these for the Client free of charge. The Client may acquire the objects at any time using expenses not yet offset and demand the retained goods.

19. Confidentiality, Storage

- 19.1. The Contractor undertakes to handle confidentially all information and knowledge that it receives in connection with the issuance of the quote or the placement of an order by the Client as a business secret and not pass it on to third parties, unless the Contractor demonstrates to the Client that the Contractor was already aware of this information upon the issuance of the order or it subsequently became accessible to the Contractor from an authorized third party with no confidentiality obligation or that it was generally accessible or subsequently became accessible, without this being attributable to the Contractor and without the Contractor being responsible for its accessibility.
- 19.2. Manufacturing for third parties and the display of products produced specifically for the Client based on its drawings or manufacturing

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specifications, publications about the products as well as the reference to an order from the Client in discussion with third parties requires the explicit prior written consent by the Client.

- 19.3. For each individual violation of this regulation in Clause 18, the Client shall be entitled to demand flat-rate compensation from the Contractor amounting to € 50,000.00. The enforcement of additional claims for further damages by the Client remains unaffected.
- 19.4. Production and delivery documents as well as other business documents that concern the Client must be held for at least fifteen (15) years, provided that no longer deadline is stipulated by law, and they must be made available to the Client upon request. The confidentiality obligation remains in effect for ten (10) years beyond the end of this Contract.
- 18.5 The Contractor is not permitted to use the Client’s brands, trademarks, registered designs, company names and other marks or to use or name the Client as a reference customer without its prior written consent. For each individual violation of this regulation, the Client shall be entitled to demand flat-rate compensation from the Contractor amounting to € 10,000.00. The enforcement of additional claims for further damages by the Client remains unaffected.
- 18.6. The Client and the Contractor consent to the storage of personal data by the other party and the forwarding of this data to companies associated with the parties, provided that the stored and forwarded data refers to the parties’ business relationship and that valid data protection regulations are observed.

20. Entry into Force, Contractual Term

- 19.1 The Contract shall enter into force on. The Contract may be terminated subject to a notice period of twelve (12) months from the end of the month. The right to terminate for just cause remains unaffected.
 Good cause includes, for example, an application for insolvency against the assets of one party, a change of control in the Contractor or a competitor of the Client holding a stake in the Contractor. In the latter two cases, the Client shall have a right of termination for good cause exclusively.
- 19.2 Regardless of the legal basis, the termination must take place in writing.
- 19.3 The termination of the Contract does not affect the effectiveness of

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binding orders placed during the term of the Contract.

21. Final Provision

20.1. Any amendments and addenda to this contract must be made in writing. This also applies to the written form clause. The same applies to the waiver of the requirement for the written form. Except for in cases of Clause 209, the written form is sufficient when the agreement or declaration takes place in a PDF document with signatures. The parties may request the additional sending of the original letter from the other party.

Insofar as email is permitted as a means of communication in this Contract, this email shall be sent to the email address notified for this purpose.

20.2. The transfer of rights and obligations from this Contract to a third party by one party requires the written approval of the other party.

20.3. Should any provision of this contract be or become legally invalid, this shall not affect the validity of the rest of the contract. The parties shall replace the invalid provision with a legally permissible provision that comes as close as possible to the invalid provision.

20.4. The termination of this Contract has no impact on provisions whose meaning and content continues beyond the termination of this Contract. This applies for Clause 198 of this Contract in particular.

22. Obligations of the Parties Following the Termination of the Contract.

21.1. At the end of the Contract, the Contractor shall fulfill the orders in accordance with this Contract, which were placed in a legally binding way during the term of the Contract with the Client. The Contractor shall also fulfill orders for its products, for which the Client can demonstrate that an order was already placed or a binding offer had been issued prior to the end of the contract, and its deadline for acceptance has not yet expired by more than ninety (90) days. In any case, the delivery of the goods will not take place later than three (3) months following the end of the Contract.

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23. Jurisdiction, Applicable Law

- 22.1. The place of jurisdiction is Jena.
- 22.2. The substantive law of the Federal Republic of Germany shall apply to the contractual relationship, but to the exclusion of its reference regulations under Private International Law and the UN Convention on Contracts for the International Sale of Goods.

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Carl Zeiss Meditec AG

Contractor

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(Place, date)

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(Place, date)

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(Signature)

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Appendix 1: Contractor Obligations

Definitions:

1. *Products* in this Contract are products, components, parts or software including the agreed documentation or test logs.
2. *Requirements specifications* in this Contract are all necessary specifications that define the specific *products* desired.
3. *Verification* is the objective evidence, documented in writing, that the *requirements specifications* have been met.
4. *Validation* is the objective evidence, documented in writing, that user requirements and intended use are satisfied and processes lead to the desired results in a reproducible way. Validation can also serve to demonstrate the fulfillment of such requirements specifications, for which no clearly definable characteristics are available for a verification.
5. *Quality management* in this Contract is a systematic process defined in writing, which reproducibly ensures that the *products* delivered meet the requirements specifications.
6. *Medical device requirements* in this Contract are the basic rules for medical devices to be used by the Contractor in the production process, including the presence and application of appropriate *quality management*, the manufacture of state-of-the-art *products* in compliance with *requirements specifications*.

General Obligations of the Contractor:

The Contractor undertakes to bear sole responsibility for the planning, organization and implementation of quality management in such a way that comprehensive control and monitoring is guaranteed and that the quality and safety requirements for the product are observed. The Client may – with prior notice – perform regular audits at the Contractor’s premises. The Contractor undertakes to provide the Client with free-of-charge advice regarding relevant questions that concern the quality of the product,

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in order to achieve a mutual understanding of quality. The following obligations must be observed in particular:

1. Within *quality management*, a valid production process to manufacture *products* must be *defined, specified in writing and monitored*.
2. The *products* delivered must meet the *requirements specifications*, and evidence is to be provided through *verification or validation*.
3. The *products'* compliance with applicable statutory, regulatory, patent and normative regulations must be ensured and monitored.
4. The products delivered must not contain any materials on the Client's banned substances list. The current list of banned substances is a component of this Contract and can be found online (www.zeiss.de/meditec at Rechtshinweise - AGB or: www.zeiss.com/meditec at Legal Information - Terms and Conditions)
5. Tools, including software, which are used in the production process and which could influence the compliance of the development results or products with the requirements specifications must be appropriate for their use and validated prior to being used for the first time. The validation must be documented in writing.
6. Tools which are used in the production process and could influence the compliance of the *products* with the *requirements specifications* must be calibrated prior to being used for the first time and regularly thereafter. The calibration must be documented in writing.
7. The Contractor must inform the Client immediately of any discontinued devices or components, changes to upstream suppliers or other market changes, insofar as these could affect the future supply to the Client.
8. Changes that concern the *requirements specifications* or the agreed quality management may only be made with the prior written consent of the Client.

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9. The Contractor must adjust the implementation of *requirements specifications* and the maintenance of its *quality management* in line with the current state of technology.
10. The Contractor must refrain from communicating or commenting on events, approval-related aspects or measures in relation to the *products* externally and without third parties without the written consent of the Client.
11. The Contractor must guarantee that the *products* are clearly identified and keep and control records on their origin, in particular where traceability is demanded.
12. Upon request from the Client, the Contractor must actively participate in processing product approvals, investigating incidents as well as corrective and preventive action (CAPA).
13. All deviations that could influence the compliance of the *products* with the *requirements specifications* must be reported to the Client immediately.
14. Requirements in the context of the CAPA process for the purpose of the implementation of statutory, normative or Client-related requirements must be implemented by the Contractor.
15. The Contractor is responsible for the comprehensible preparation, maintenance, storage and transfer of technical documentation (including software) and records on each *product*.
16. All specification and evidence documents that are a component of the *product* must be reviewed by at least two people and approved via signature.
17. Technical documentation must be made available immediately upon the Client's request.
18. All documentation regarding the development, production and procurement process must be stored for at least 15 years, to be handed over to the Client upon request and, in the event of the dissolution of the Contractor, to its legal

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successor. After the expiry of this period, the documents must be offered to the Client for further use.

- 19. Upon the Client’s request, the Contractor shall actively cooperate in the preparation and conduct of third party audits (providing copies of documents, making contact persons available). The Contractor shall ensure access to all relevant information which demonstrates the implementation of the contractual content. The costs for the third-party auditor are borne by the Client.
- 20. The Contractor shall ensure cooperative collaboration and that access is granted to its business premises for the purposes of product or quality management audits, third-party audits by or in the presence of the Client or by a person the Client has appointed.
- 21. The Contractor must implement itself and assign to any subcontractors (suppliers, service providers, logistics firms, laboratories, calibration services) its obligations towards the Client to ensure product quality, in particular obligations to implement statutory requirements (vigilance, traceability), including within the area of responsibility of this sub-contractor.

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