Quality Assurance Agreement (QAA)

between

Carl Zeiss Company
Address
Germany

hereinafter referred to as “ZEISS”

and

SUPPLIER A
Sample Street 1
1234 Sample City
Sample State

hereinafter referred to as “SUPPLIER”

ZEISS and SUPPLIER hereinafter also referred to as “CONTRACTING PARTIES”

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1. Preamble

This Quality Assurance Agreement (hereinafter called the QAA) specifies and governs all the designated measures between the PARTIES as minimum requirements for the management system of the PARTIES, the purpose of which is to guarantee and improve the quality of the products which are to be delivered and the services to be performed (hereinafter called the "GOODS and SERVICES") with regard to the joint "zero defects objective".

2. General provisions

This QAA is divided into

a) the general part containing fundamental provisions
b) Appendix A for special quality assurance regulations

3. Scope

The provisions of these QAA apply in conjunction with the provisions of the Framework Agreement, in so far as such an agreement was concluded between the PARTIES and with the General Terms and Conditions of Purchase of ZEISS for the development, manufacture and supply of GOODS and SERVICES from the SUPPLIER. In the event of any conflict of the content of the Frame Agreement and/or the General Terms and Conditions of Purchase of ZEISS with this QAA, the following order of priority will apply:

1. Framework agreement
2. These QAA and its annexes
3. ZEISS`s general terms and conditions of purchase.

The QAA applies to all SERVICES provided by the SUPPLIER to ZEISS.

The scope of these QSV may be extended to affiliated companies of Carl Zeiss AG and/or the SUPPLIER by means of a written accession agreement. The accession agreement may contain separate provisions to meet specific requirements.

4. The SUPPLIER’s management systems

4.1. Quality management system

The SUPPLIER undertakes to implement, maintain, and continuously improve a documented quality management system (hereinafter referred to as the QMS) that meets the requirements of ISO 9001 (in its currently valid version).

A certified QM system in accordance with ISO 9001 or a comparable standard (ISO 13485, EN 9100, IATF 16949, VDA 6.1) is desirable.

5. Management systems of subcontractors

The SUPPLIER shall require its subcontractors to comply with the obligations assumed by the SUPPLIER under this contract. ZEISS may require the SUPPLIER to provide documented evidence that the SUPPLIER has verified the effectiveness of the quality management systems of its subcontractors. Likewise, ZEISS may require the SUPPLIER to submit test and quality records from its subcontractors.

6. Specifications, statutory requirements, and regulations

The mandatory basic principle for the provision of the SERVICES shall be the specifications underlying the order, including the applicable documents.

The SUPPLIER undertakes to comply with all country-specific laws of the CONTRACTING PARTIES when providing the SERVICES.

7. Change management

The SUPPLIER must establish its own procedure to ensure that any intended change to the approved scope of services or delivery (e.g., changes to the technical design, specifications, production processes and procedures, additives and operating materials, or the use of equivalent or alternative products) is evaluated, verified, validated, and approved by the SUPPLIER with regard to its potential impacts prior to implementation. In addition, the SUPPLIER must maintain appropriate records.

During the evaluation, the SUPPLIER must verify whether the planned change requires approval by ZEISS prior to its implementation.

In principle, all changes are subject to approval by ZEISS if they alter the product characteristics (generally in terms of form, fit, and function).

The following change criteria are generally subject to approval by ZEISS:

- Changes to the specification and other procurement documents
- All changes to the design (including the use of alternative components for discontinued parts)
- All changes to components or assemblies used in safety-critical applications
- Changes affecting the function and performance of the scope of delivery
- Changes affecting service life or usability
- Changes to or relocation of production facilities
- Change of subcontractors
- The outsourcing of production of complete units to subcontractors (third parties)
- All changes to software and/or firmware (product-related)
- Changes to any interfaces (electrical, mechanical, or functional)

ZEISS units may individually expand upon these criteria for the approval requirement of changes based on business needs. These must be agreed upon in a binding manner in the procurement documents or in the appendix to the QAA.

If at least one of the criteria listed applies, ZEISS must be notified immediately in writing of the proposed change and written approval must be obtained from ZEISS in accordance with the agreed procedure before the planned change is implemented.

Changes initiated by ZEISS must also be evaluated by the SUPPLIER through a manufacturability assessment (Section 8.1). This procedure also applies to projects that are still in the development phase.

These change management requirements also cover intended changes at or by subcontractors.

8. Quality planning

The SUPPLIER shall carry out quality planning with the goal of ensuring compliance with the performance specifications agreed upon with ZEISS, enabling a smooth product launch (“First Time Right”), and guaranteeing a reproducible production process. This planning covers both the SERVICES provided by the SUPPLIER and its purchased parts or services and includes

structured work steps for performance and process qualifications. The SUPPLIER shall define and document, on its own responsibility, the work steps and measures by which it achieves this objective.

Quality planning includes at least the following steps:

- Conducting a manufacturability assessment
- Identification of critical/special characteristics and, based on this, the planning or definition of design and control measures
- Measures, including planning for the qualification of the product's measurement/inspection process and, if necessary, for process capability
- Planning and qualification of manufacturing and assembly equipment and processes
- Planning and development of test plans, including test methods and test tools
- Planning and conducting quality assessments
- Definition of preventive quality measures for suppliers/subcontractors
- Identification and reduction of risks in the production process using appropriate methods (e.g., through an FMEA or a risk analysis).

8.1. Feasibility study

The SUPPLIER agrees to conduct a feasibility study for requests regarding new or modified SERVICES, taking into account technological, logistical, and quality-related aspects (quality objectives) based on the underlying specifications, including all applicable documents. This assessment must be submitted to ZEISS along with the quotation.

The feasibility study must also be conducted in the event of changes (see Change Management).

Quotations from the SUPPLIER to ZEISS require a positive result of the feasibility study (all requirements are met in full). In the event of a limited or negative result, the matter must be reviewed with ZEISS in advance of the submission of a quotation.

The form to be used for the feasibility study can be downloaded from the download section of the supplier portal on the ZEISS website if needed. Alternatively, the supplier's own feasibility study may be used in place of the ZEISS form, provided it covers all the required content of the ZEISS form.

8.2. Critical characteristics

All performance and process characteristics specified by ZEISS, as well as critical characteristics, must be complied with by the SUPPLIER. In addition to the requirements defined by ZEISS, the SUPPLIER must identify its own critical or special characteristics (hereinafter "Critical Characteristics") and make them available in all relevant documents agreed upon with ZEISS (such as drawings, work/inspection plans, etc.), and the corresponding characteristics must be marked therein. These characteristics must be taken into account, monitored, and documented by the SUPPLIER during the planning of the manufacturing process as well as in subsequent series production.

If process capability is required by ZEISS, the Critical Characteristics must be taken into account accordingly and verified by the SUPPLIER.

8.3. Inspection planning / Inspection equipment

The SUPPLIER shall prepare an inspection plan that specifies all characteristics to be inspected, particularly critical characteristics, along with the associated inspection equipment, methods, frequencies, and the type of documentation for each work step.

If the SUPPLIER does not have all the necessary test equipment available for SERVICES or characteristics of SERVICES, the SUPPLIER must ensure their procurement and qualification.

For all inspection processes and inspection equipment, including requirements for personnel, equipment, environment, methods, etc., the SUPPLIER must demonstrate and document their capability, e.g., using a measurement system analysis (MSA).

If test equipment and/or test software is provided to the SUPPLIER by ZEISS, the SUPPLIER must handle this test equipment with due care to protect it from damage, contamination, deterioration, or other factors that could impair measurement accuracy, and must include it in the SUPPLIER's test equipment control system.

The SUPPLIER must subject the test equipment and standards it uses to regular and systematic monitoring (calibration). The use of a nationally recognized calibration body or a calibration body accredited according to ISO 17025 (accredited laboratory) must be ensured and documented by the SUPPLIER in a traceable manner. Upon request, the relevant documentation must be made available to ZEISS.

8.4. Production process and part approval

Production process and part approval by ZEISS is generally based on an initial sample inspection. If necessary and upon prior notice, ZEISS will conduct a process acceptance inspection at the SUPPLIER's premises and, if applicable, within the supply chain.

This is intended to ensure that all activities related to process and quality planning are successfully implemented and completed.

8.5. Continuous improvement process

The SUPPLIER shall ensure, through a continuous improvement process, that the QM system and the product realization processes are further developed and that the shared "zero-defect" goal can be achieved. Furthermore, this is intended to minimize the costs of quality assurance and defect management at both ZEISS and the SUPPLIER. To this end, the SUPPLIER must employ suitable problem-solving methods and carry out targeted monitoring and control of the production process using statistical methods.

The focus is on:

- Increasing process capability by reducing variation and centering the processes;
- Preventive error management, which prevents avoidable errors before they occur
- Limiting the frequency of inspections to the necessary extent;
- Sustainable error management through the identification of root causes and the permanent elimination of error causes, as well as preventive measures against the occurrence of similar nonconformities in other areas.

9. Quality assurance by the SUPPLIER

9.1. Quality inspection by the SUPPLIER

The quality inspection to be performed by the SUPPLIER must cover the entire process from receipt of the material by the SUPPLIER through the entire manufacturing process to the shipment of the finished SERVICES in order to ensure compliance with all ZEISS quality requirements.

The SUPPLIER undertakes to incorporate its suppliers, as well as, where applicable, development partners or any third parties involved who are necessary for the manufacture or

quality assurance of the agreed-upon SERVICES, into its quality management system or to ensure the quality of the upstream supplies itself.

In accordance with the inspection planning in Section 8. Quality Planning, records of the inspections and measurements must be maintained and made available to ZEISS upon request. This also applies to subcontractors.

9.2. Initial Samples / Initial Sample Inspection

If ZEISS orders initial samples from the SUPPLIER, the initial samples must be manufactured under series production conditions using standard production equipment. The initial samples must fully comply with the specifications stated in the ZEISS order or provided with it.

The initial sample inspection must be documented by the SUPPLIER in an initial sample inspection report containing all test characteristics specified in the specifications and provided as agreed with ZEISS, e.g., as a digital document. The SUPPLIER must ensure that the results of the initial sample inspection are properly documented in the template agreed upon with ZEISS for this purpose and must ensure that the initial samples and the inspection report can be matched to one another at any time and that the initial samples are clearly identifiable as such to ZEISS without opening the packaging.

If the initial sample inspection report contains deviations from the relevant specification, the report and the associated initial samples may only be submitted with the written approval of ZEISS. The deviations must be clearly marked

Following a cross-check by ZEISS or a third party commissioned by ZEISS, the SUPPLIER shall receive the acceptance decision for the initial sample inspection. Series production may only commence upon receipt of the “Approved” acceptance decision. If the initial sample test report is rejected or only receives conditional approval, the SUPPLIER must immediately initiate corrective actions and, upon agreement with ZEISS, conduct a new initial sampling or re-sampling of initial samples that comply with the specifications.

A repeat initial sampling / re-sampling may also be required in the following cases:

- In the event of changes to specifications, process changes (process changes, tooling changes, changes involving subcontractors, etc.), or production relocations;
- If the SUPPLIER has not provided any SERVICES to ZEISS for a period of 18 months or longer;

If a change must be made due to the SUPPLIER’s fault, the SUPPLIER shall bear all costs incurred in connection with the repeat initial sample inspection (including those for ZEISS).

9.2.1. Procedure for an Initial Sample Inspection

The initial sample inspection must proceed in the following steps:

1. Production of the initial samples under series production conditions using the manufacturing equipment and methods employed in series production;
2. Inspection of the initial samples in accordance with agreed inspection specifications and using suitable measuring equipment;
3. Documentation of the test results in a first-article inspection report;
4. Delivery of the initial samples with the corresponding initial sample inspection reports;
5. If necessary, re-inspection of selected characteristics by ZEISS and documentation of the results in the initial sample inspection report by ZEISS;
6. ZEISS internal approval or rejection for series production;

7. Notification of the SUPPLIER by ZEISS regarding the result of the initial sample inspection; and
8. Definition of further measures in consultation with the SUPPLIER, if necessary.

9.3. Manufacturing, product marking, traceability, test certificate, packaging

9.3.1. Process disruptions / Quality deviations

In the event of process disruptions and quality deviations, the SUPPLIER shall analyze the causes, initiate corrective actions, verify their effectiveness, and document this procedure.

If the SUPPLIER is unable to meet the required specifications, it must obtain special approval from ZEISS prior to delivery.

9.3.2. Preventive maintenance / servicing

The SUPPLIER shall ensure the provision of SERVICES in accordance with the agreed delivery quantities and dates. To prevent disruptions and machine, equipment, and tool failures, the SUPPLIER shall perform preventive maintenance.

9.3.3. Labeling

The SUPPLIER undertakes to label the SERVICES and the packaging in accordance with the agreements made with ZEISS. The allocation of the delivered SERVICES to the order must be guaranteed. The SUPPLIER must ensure that the labeling of the packaged SERVICES remains legible during transport and storage.

9.3.4. FIFO Principle / Traceability

The SUPPLIER undertakes to comply with the FIFO principle (First In – First Out). If traceability is required, the SUPPLIER must ensure traceability to the required extent for the SERVICES it delivers.

9.3.5. Ownership by ZEISS

Manufacturing and testing equipment provided by ZEISS, in particular equipment and facilities provided in connection with the procurement of SERVICES, must be marked as ZEISS property. The SUPPLIER is responsible for ensuring the integrity and proper functioning of such equipment and must arrange for its maintenance and repair, unless otherwise specifically provided for in other agreements (e.g., a loan agreement).

9.3.6. Test Certificate

Quality inspection certificates must be provided by the SUPPLIER along with the SERVICE in accordance with ZEISS's requirements.

9.3.7 Packaging

The type of packaging shall be as specified in the respective specification. Unless otherwise agreed, the type of packaging shall be determined by the SUPPLIER, taking into account that the delivered items are protected against foreseeable, usual loads and environmental influences during transport and storage and that the performance/component properties are not altered. If ZEISS specifies special transport conditions, these must be strictly adhered to for the packaging.

ZEISS is entitled to reject deliveries from the SUPPLIER in case of defective packaging, damaged containers, or containers with unclear labeling, and to charge the SUPPLIER for any additional costs incurred by ZEISS as a result.

9.4. Documentation of quality data

The SUPPLIER must maintain documentation of quality data (quality records) in accordance with ZEISS's respective requirements. This includes, in particular:

- Documentation of production data (test reports, initial sample test reports, quality control charts, process data from parameter monitoring, etc.),
- Documentation of service life and reliability tests,
- Documentation of test equipment monitoring,
- Feasibility study,
- Corrective and preventive actions.

ZEISS is entitled to inspect and receive the supporting documents. This also applies to documents from subcontractors.

Unless otherwise agreed, all relevant supporting documents must be archived and protected for at least 10 years from the delivery date of the SERVICE to ensure legibility throughout the archiving period. Any additional legal obligations regarding documentation and archiving remain unaffected by this provision.

10. Goods Receipt / Incoming Goods Inspection at ZEISS

Upon delivery of the SERVICES, ZEISS merely checks whether they correspond to the ordered quantity and type and whether there is any transport damage or defects visible on the outside of the packaging. ZEISS also generally conducts random checks of the accompanying quality documents and certificates.

ZEISS reserves the right to conduct further inspections in individual cases.

The SUPPLIER must align its quality management system and its quality assurance measures with this reduced incoming goods inspection at ZEISS.

ZEISS shall notify the SUPPLIER in writing of any defects in the delivered SERVICE as soon as they are discovered in the course of normal business operations. In this regard, the SUPPLIER waives the right to object on the grounds of a delayed notice of defects.

11. Special approval prior to delivery of the SERVICES to ZEISS

If the SUPPLIER is unable to fulfill an agreed-upon SERVICE in accordance with the contract due to non-conformities identified prior to delivery, and if the deviations cannot be rectified before the agreed-upon delivery date despite special efforts and immediate measures, the SUPPLIER may, in exceptional cases, request ZEISS's approval for the delivery of a non-conforming SERVICE by submitting an application for special approval.

However, the urgency of the supply situation must always first be clarified with the buyer at ZEISS, and efforts must be made to eliminate the deviations through rework or remanufacturing.

The causes of the identified deviations must be analyzed immediately, and appropriate corrective measures must be implemented to permanently prevent the recurrence of the deviations.

The request for special approval must always be submitted in writing using the ZEISS form to the ZEISS customer. The request must always include a detailed description of the deviation, the identified cause of the defect, and the corrective actions taken with a planned implementation date.

ZEISS evaluates the request for special approval with regard to the potential impacts and risks of the deviations through Quality Management, Technical Development, and other departments.

Following a final evaluation, ZEISS will notify the SUPPLIER of the decision regarding special approval. The following decisions are possible:

1. Acceptance of the delivery with special approval subject to subsequent rectification or an extension of the warranty obligation,
2. Acceptance of the delivery with special approval subject to a reduction in the purchase price,
3. Rejection of the defective delivery and refusal of special approval.

A combination of options 1 and 2 of the aforementioned decisions is also possible.

All deliveries made on the basis of an accepted special release must be clearly marked. A copy of the special release signed by ZEISS must be enclosed with the SERVICES upon delivery.

Any waiver of warranty claims regarding defective performance declared by ZEISS within the scope of the special release does not constitute a waiver of warranty claims based on other defects in the SERVICES or the DELIVERIES.

12. Complaints / Claims

In the event of complaints, these shall be handled by the SUPPLIER using a prescribed, structured problem-solving method that ensures that the defects are sustainably and permanently rectified. ZEISS shall decide on a case-by-case basis which of the following methods is to be used:

- Statement from the SUPPLIER,
- Custom report format, the content of which meets all requirements of the currently valid version of ISO 9001 regarding nonconformities,
- 8D report.

The SUPPLIER must provide feedback and submit reports in a timely manner, in accordance with the deadlines and requirements specified by ZEISS.

13. Supplier Evaluation

ZEISS regularly conducts supplier evaluations based on the quality of the SERVICES provided by the SUPPLIER, which are taken into account, among other things, in the selection of suppliers and in further cooperation with the SUPPLIER. Furthermore, the supplier evaluation serves as the basis for jointly defining quality objectives with the SUPPLIER in order to achieve continuous improvement. If these targets are not met, the CONTRACTING PARTIES may agree on a supplier development plan on a case-by-case basis to ensure that the SUPPLIER’s delivery performance meets the planned targets, or a reduction in the scope of supply may be implemented, up to and including the suspension of the SUPPLIER from new orders.

The basis for the evaluation is supplier-specific logistics and quality data (HARDFACTS). For SUPPLIERS with “Managed Supplier” or “Strategic Partner” status, additional criteria such as the QM system, occupational safety/environmental management system, logistics, price level, technology, and commercial requirements (SOFTFACTS) are evaluated. Compliance with the regulations agreed upon in this QAA is also taken into the supplier evaluation.

14. Audits

The SUPPLIER grants ZEISS or a third party designated by ZEISS or a client of ZEISS the right to conduct audits.

The audit may be conducted as a system, process, product, or combined audit. In all cases, audits are conducted following prior notice and coordination. If necessary, the SUPPLIER will enable audits to be conducted at short notice if so requested by ZEISS., for example, due to non-conformities at the supplier or in the supply chain, can respond and assist in resolving the issue. The SUPPLIER shall grant ZEISS and, where necessary, its customers access all business premises, testing facilities, warehouses, and surrounding areas, as well as access to all audit-relevant documents and to tools, testing equipment, and aids. Necessary and reasonable restrictions by the SUPPLIER to protect its company secrets will be accepted during this process.

If quality issues arise that are caused by a subcontractor, the SUPPLIER shall take all possible steps to enable ZEISS and, if necessary, its customers to conduct an audit of that subcontractor.

If the sub-contractor has legitimate objections to the participation by ZEISS or its customer in an audit, ZEISS is prepared to arrange for the audit to be conducted at the SUPPLIER'S expense by a neutral third party organization representing the interests of ZEISS or ZEISS'S client.

ZEISS shall notify the SUPPLIER of the audit results. If, in the opinion of ZEISS, corrective actions are necessary, the SUPPLIER will immediately undertake to implement the corrective actions set out in the audit report within the period allowed and in an effective manner and to inform ZEISS of this..

The documents, records, and information exchanged between the CONTRACTING PARTIES as part of the audit are subject to confidentiality in accordance with the provisions agreed upon between the CONTRACTING PARTIES.

15. Term and Termination

This QAA will become effective upon signature by the last CONTRACTING PARTY to sign and shall apply to all deliveries of SERVICES made by the SUPPLIER to ZEISS from the date becomes effective.

Each CONTRACTING PARTY may terminate these QAA by giving 6 months' notice at the end of any month.

16. Final Provisions

16.1. Written Form

Amendments and/or additions to this QAA are effective only if they are executed as a separate document and signed by both ZEISS and the SUPPLIER. The parties agree that electronic signatures via AdobeSign, DocuSign, or a comparable platform satisfy the requirement of written form.

16.2. Severability Clause

The ineffectiveness or invalidity of one or more provisions of this QAA shall not lead to its invalidity overall. The CONTRACTING PARTIES will replace ineffective or invalid provisions through such effective provisions which are approximate as closely as permissible to the commercial intent of the invalid or unenforceable provisions. This will also apply accordingly to the resolution of lacunae.

16.3. Governing Law

This QAA is governed by the law of the Federal Republic of Germany. The UN Convention on Contracts for the International Sale of Goods of April 11, 1980, does not apply.

16.4. Place of Jurisdiction

The exclusive place of jurisdiction for all disputes arising from and in connection with this QAA is the registered office of ZEISS for both CONTRACTING PARTIES. However, ZEISS may, at its discretion, also bring an action at the Supplier's place of jurisdiction.

16.5. Applicable Documents

Appendix A: Special Quality Assurance Regulations

17. Signatures

These QAS is prepared in two identical originals, one of which is provided to each party. The copies are only effective if all signatures have been applied.

Carl ZEISS [Company]	SUPPLIER
_____	_____
Place, Date	Place, Date
_____	_____
Name:	Name:
Title:	Title:
_____	
Name:	
Title:	

Appendix A: Special Quality Assurance Regulations

No additional regulations were agreed upon regarding the general section of the QAA.

Carl ZEISS [Company]	SUPPLIER
_____	_____
Place, Date	Place, Date
_____	_____
Name:	Name:
Title:	Title:
_____	
Name:	
Title:	