Quality Assurance Agreement (QAA)

between

Carl Zeiss Company
Address
Germany

hereinafter referred to as “ZEISS"

and

SUPPLIER A
1 Main Street
1234 City
Country

hereinafter referred to as the “SUPPLIER"

ZEISS and the SUPPLIER are hereinafter also referred to as the “PARTIES "

1. Contents

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

This QAA is divided into

a) the General part containing fundamental provisions
b) Attachment A for particular provisions on Quality Assurance

3. Scope of application

The provisions of this QAA apply in conjunction with the provisions of the Frame 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. The Frame Agreement
2. This QAA and its Attachments
3. The General Terms and Conditions of Purchase of ZEISS

The QAA applies to all the SUPPLIER'S GOODS and SERVICES provided to ZEISS.

The scope of application of the QAA may be extended to affiliated companies (§§ 15 ff of the German Public Companies Act [*Aktiengesetz, AKTG*]) of Carl Zeiss AG and/or the SUPPLIER by means of a written accession agreement. If necessary, separate provisions will be concluded in the accession agreement to give consideration to the separate requirements.

4. The SUPPLIER'S Management systems

4.1. Quality Management system

The SUPPLIER undertakes to introduce, maintain and develop a Quality Management system (hereinafter called a "QM system) the content of which complies with the requirements of ISO 9001 (as amended).

A certified QM system according to ISO 9001 or a comparable standard (ISO 13485, EN 9100, ISO TS 16949, VDA 6.1) is desirable.

In so far as it proves to be necessary and is expedient, the SUPPLIER will support and promote the endeavors of ZEISS to improve and develop the SUPPLIER'S QM system.

4.2. Environmental management

The SUPPLIER undertakes to accept and implement the content of the ZEISS environmental policy which can be seen at www.zeiss.com/responsibility in the Internet.

A certified environmental management system according to ISO 14001or a comparable environmental management standard is desirable.

If so requested by ZEISS, the SUPPLIER will demonstrate appropriate recycling and disposal concepts for GOODS and SERVICES

4.3. Health and Safety

The PARTIES undertake to promote and ensure the health of their employees on an ongoing basis. Compliance with country-specific laws, standards and regulations on health and safety is obligatory for the PARTIES.

A certified health and safety management system is desirable.

5. Sub-contractors' management systems

The SUPPLIER will place their subcontractors under an obligation of compliance with the same obligations as assumed by themselves under this Agreement. ZEISS is entitled to demand documentary evidence from the SUPPLIER demonstrating that the SUPPLIER has convinced themselves of the effectiveness of their subcontractors' management systems. ZEISS may also demand that the SUPPLIER submits written testing, inspection and quality evidence in respect of their subcontractors.

6. Specifications, statutory requirements and regulations

The mandatory basic principle for the supply of the GOODS and SERVICES is the specifications including the other applicable documents which are fundamental to the order.

When supplying the GOODS and SERVICES, the SUPPLIER undertakes to comply with all applicable country-specific laws of the PARTIES.

7. Change management

The SUPPLIER must establish own process to ensure that every intended alteration to the approved scope of the GOODS and SERVICES (e.g. alterations to the technical as-built condition, specification, production processes and sequences, additives and operating materials as well as the use of equivalent of alternative products) must be assessed, verified, validated and approved by the SUPPLIER with regard to potential effects prior to their implementation. The SUPPLIER must also maintain appropriate records.

During the assessment process the SUPPLIER must examine whether there is an obligation to obtain the approval of ZEISS for the planned alteration prior to its implementation.

In principle, all alterations are subject to the approval of ZEISS if product properties (normally in terms of form/fit/function) are amended by such alterations.

The following amendment criteria are subject to the approval of ZEISS as a matter of principle:

- Amendments of the specification and other procurement documents
- All modifications of the as-built condition (including the use of alternative components for discontinued parts)
- All modifications of components or modules which are used in a safety-relevant capacity
- Amendments which influence the function and performance of the scope of supply
- Amendments which influence the working life or serviceability
- Alterations to and the relocation of production sites
- Changes in subcontractors
- The outsourcing of the manufacture of complete units to sub-contractors (third parties)

- All amendments to software and/or firmware (product related)
- Amendments to any interfaces (electrical, mechanical or functional)

Detailed definitions of these criteria for the mandatory approval of amendments may be expanded on a case by case basis by ZEISS units as a result of business imperatives. These must be agreed in the procurement documents or in the attachment to the QAA in a manner such that they are mandatory.

If at least one of the above-mentioned criteria applies, ZEISS must be informed immediately in writing about the intended change and written approval must be obtained from ZEISS in accordance with the agreed procedure before the planned change is implemented.

Amendments initiated by ZEISS must also be assessed by the SUPPLIER in a feasibility study (Clause 8.1). This procedure also applies to projects that are still in the development phase.

These requirements for change management also include planned changes at or by sub-contractors.

8. Quality planning

The SUPPLIER will carry out quality planning with the goal of safeguarding the performance specifications agreed with ZEISS, permitting a smooth start to production (first time right) and guaranteeing a reproducible production process. This planning will include both the GOODS and SERVICES provided by the SUPPLIER as well as the SUPPLIER'S bought-in parts/services and will contain structured steps for performance and process qualification. The SUPPLIER will, on its own responsibility, specify these steps and will document the individual operations and actions taken to achieve this goal.

The quality planning will include the following steps as a minimum:

- Conducting a feasibility study
- Identification of critical/special characteristics and, as the next step, the planning and definition of design and control measures
- Measures, including planning for the qualification of the product measuring/testing process and, if necessary, for the process capability
- Planning and qualification of the production equipment, assembly equipment, and processes
- Planning and development of testing and inspection plans including testing and inspection methods and tools
- Planning and implementation of quality assessments
- Definition of preventive quality measures at the premises of suppliers /subcontractors
- Determination and reduction of risks in the production process by suitable methods (e.g. by an FMEA)

8.1. Feasibility study

On receiving inquiries for new or modified GOODS and SERVICES, the SUPPLIER is to conduct a feasibility study with regard to technological, logistical and quality-relevant aspects (quality objectives) based on the underlying specifications including all other applicable documents. This must be submitted to ZEISS along with the offer.

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

Offers to ZEISS presuppose a successful outcome of the feasibility study (all requirements are met in full). In the event of a negative outcome or an outcome indicating restrictions, the matter must be reviewed with ZEISS in advance of the submission of an offer.

If necessary, the form to be used for feasibility study, will be provided by ZEISS.

8.2. Critical Characteristics

All performance and process characteristics specified by ZEISS must be met by the SUPPLIER. In addition to the requirements defined by ZEISS, all characteristics that are critical or special for ZEISS (hereinafter referred to as “Critical Characteristics”) must be identified by the SUPPLIER and provided in all relevant documents agreed with ZEISS (such as drawings, test plans, etc.) and the corresponding characteristics marked in such documents. These characteristics must be taken into account and monitored by the SUPPLIER in the planning of the manufacturing process and in subsequent series production.

In so far as process capability is required by ZEISS, account must be taken of Critical Characteristics accordingly and substantiated by the SUPPLIER.

8.3. Planning of testing and inspection/test equipment

The SUPPLIER will create a testing and inspection plan which will include all characteristics (and particularly Critical Characteristics) to be inspected and tested along with the associated test equipment, methods, frequencies and type of documentation for every procedure.

If all the test equipment necessary for the SUPPLIER'S GOODS and SERVICES or features of the GOODS and SERVICES are not on hand at the SUPPLIER'S premises, the SUPPLIER must ensure that they are procured and qualified.

The capability of all inspection processes and measuring equipment, including the requirements of staff, equipment, the environment and methods, etc. must be verified and documented by the SUPPLIER, for example by means of a Measuring System Analysis (MSA).

If testing equipment and/or software is provided to the SUPPLIER by ZEISS, the SUPPLIER must have procedures to protect equipment from damage, contamination, deterioration, or other factors that may adversely affect the integrity of the equipment and includes such equipment and/or software in the test equipment control of the SUPPLIER.

The SUPPLIER must subject the test equipment and standards it uses it to regular and systematic monitoring (calibration). Use of a National Metrology Institute (NMI) or calibration facility accredited to ISO 17025 be ensured and comprehensibly documented by the SUPPLIER. If so requested, the corresponding documents must be made available to ZEISS.

8.4. Approval of the production process and of the GOODS and SERVICES

Approval by ZEISS of the production process and of the GOODS and SERVICES is usually given based on an initial sample inspection. If required and after prior notification, ZEISS will perform a process acceptance test in the SUPPLIER'S premises. This is intended to ensure that all the activities for the process and quality planning have been successfully performed and completed.

8.5. Continuous improvement process

By means of a continuous improvement process the SUPPLIER will ensure that the QM system and the product manufacturing process are capable and controlled and that the common "zero defects" objective can be achieved. The intention of this is also to reduce the financial costs for

Quality Assurance and fault management both for ZEISS and the SUPPLIER to a minimum. In order to achieve this, the SUPPLIER must employ systematic problem-solving methods and perform targeted monitoring and control of the production process using statistical methods.

Here the focus will be on:

- Increasing process capability by reducing variations and centering the processes;
- Preventive fault management which prevents avoidable faults before they arise
- Limiting testing frequency to the extent necessary;
- Sustainable fault management by the identification of the root causes and the permanent removal of the causes of faults as well as preventive measures to combat repeated faults.

9. Quality assurance by the SUPPLIER

9.1. Quality inspection and testing by the SUPPLIER

In order to guarantee compliance with all the ZEISS quality requirements, the quality inspection and testing by the SUPPLIER must extend from receipt of the material in the SUPPLIER'S premises, through the entire production process and on to the dispatch of the finished GOODS and SERVICES.

The SUPPLIER undertakes to incorporate all sub-contractors and, if applicable, development partners as well as all involved third parties who are needed for the manufacture or Quality Assurance of the agreed GOODS and SERVICES into their Quality Management system or to ensure the quality of the initial deliveries themselves.

Records of the tests and measurements must be kept and made available to ZEISS if requested. This also applies to sub-contractors.

9.2. Initial sample / initial sample testing and inspection

If ZEISS orders initial samples from the SUPPLIER, the initial samples must be manufactured under volume production conditions with standard production facilities. The initial samples must comply with the specification indicated or supplied by ZEISS with the order.

The testing and inspection of the initial sample must be documented by the SUPPLIER in an initial sample test report with all the inspection criteria indicated in the specifications, and submitted to ZEISS by the agreed route (by email, supplier portal or mail) in a form that can be assessed by electronic means. An additional hard copy of the documentation must be included with the delivery of the initial sample. The SUPPLIER must be sure to submit the proper documentation of the results of the initial sample testing and inspection in the form specified by ZEISS for this purpose, and must take care to ensure that the initial sample and the testing and inspection report can be matched with each other again at any time and that the initial samples are clearly identifiable as such for ZEISS without opening the packaging.

If the inspection and test report on the initial sample should contain deviations from the relevant specification, the report and the associated initial sample may only be submitted with the written consent of ZEISS. The deviations must be clearly marked in the report.

The SUPPLIER will receive the usage decision after further testing of the initial sample by ZEISS or an independent third party engaged by ZEISS. Volume production may only commence with the "approved" usage decision. If the testing and inspection report on the initial sample is rejected or is the subject of only restricted approval, the SUPPLIER must immediately initiate corrective measures and, after agreement with ZEISS, resubmit initial samples conforming to the specification (re-sampling).

Re-sampling may also be required in the following cases:

- In the case of modified specifications, process changes (process changes, tool changes, changes to or at the premises of subcontractors, etc.) and in the event of the relocation of production;
- If the SUPPLIER has not supplied any GOODS and SERVICES to ZEISS for a period of 18 months or longer; or
- At the request of ZEISS.

If the SUPPLIER has caused the changes, the SUPPLIER will bear the costs incurred in the course of the new initial sample testing and inspection.

9.2.1. Initial testing and inspection sequence

The initial sample testing inspection must be carried out in the following steps:

1. Manufacture of the initial sample under volume production conditions using production equipment and methods used in volume production;
2. Testing of the initial sample in accordance with the agreed test specifications and capable measuring equipment;
3. Documentation of the test results in an initial sample test and inspection report;
4. Delivery of initial samples along with the relevant initial sample test and inspection reports;
5. If applicable, further testing and 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 volume production;
7. Information passed to the SUPPLIER by ZEISS on the result of the initial sample testing and inspection; and
8. Definition of further measures in consultation with the SUPPLIER, if necessary.

9.3. The manufacture and marking of products, traceability, test certificates, packaging

9.3.1. Process disruptions/quality deviations

In the event of process disruptions and quality deviations the SUPPLIER will analyze the causes, initiate corrective measures, check their effectiveness and document this procedure.

If the SUPPLIER is unable to supply any GOODS and SERVICES in accordance with the required specifications, he must obtain a special approval from ZEISS prior to delivery.

9.3.2. Preventive maintenance / repairs

The SUPPLIER will ensure that GOODS and SERVICES are supplied in accordance with the agreed volumes and delivery schedules. The SUPPLIER will undertake preventive maintenance procedures in order to avoid disruptions and break-downs of machines, equipment and tools.

9.3.3. Marking

The SUPPLIER undertakes to mark the GOODS and SERVICES and the packaging in accordance with the agreements concluded with ZEISS. It must be possible to correlate the GOODS and SERVICES which are supplied with the order. The SUPPLIER must ensure that after packaging, the marking of the GOODS is legible during transportation and storage.

9.3.4. The FIFO principle / traceability

The SUPPLIER undertakes to abide by the FIFO (first in, first out) principle. In so far as traceability is required, the SUPPLIER must ensure that the GOODS and SERVICES he supplies are traceable to the extent required.

9.3.5. ZEISS property

Manufacturing and testing equipment which are supplied by ZEISS and particularly equipment and devices supplied in the context of the purchase of GOODS and SERVICES must be marked as the property of ZEISS. The SUPPLIER is responsible for the freedom from damage and proper function of the items supplied by ZEISS and will initiate to repair and maintain them, unless this is specified in other provisions (e.g. loan agreement).

9.3.6. Inspection certificate

At the request of ZEISS, the SUPPLIER will supply quality testing and inspection certificates with the GOODS and SERVICES as required by the relevant order. The quality of the purchased raw materials must be documented by the SUPPLIER in an acceptance test certificate (as specified by ZEISS).

9.3.7. Packaging

The type of packaging will be as stipulated in the relevant specification. If no special agreements are made, the type of packaging will be determined by the SUPPLIER, ensuring that the delivery items are protected from the foreseeable, usual loads and environmental influences during transportation and storage and that the properties of the goods/components are not altered. If special transport conditions are specified by ZEISS, they will be mandatory for the packaging.

ZEISS is entitled to refuse supplies in defective packaging, damaged boxes and boxes without clear marking and to invoice the SUPPLIER with the additional costs incurred by ZEISS as a result of such supplies.

9.4. Documentation of quality data

The SUPPLIER must document the quality data in accordance with the relevant requirements of ZEISS (quality records). This will include in particular:

- Documentation of the manufacturing data (inspection and testing reports, initial sample testing and inspection reports, quality control charts, process data from parameter monitoring, etc.);
- Documentation of the product lifecycle and reliability tests
- Documentation of test equipment monitoring.
- Feasibility study
- Corrective and preventive action

ZEISS is entitled to have sight of the documentary evidence and obtain copies thereof. This also applies to sub-contractors' documents.

All relevant documentary evidence must be archived for at least 10 years from the date of delivery of the GOODS and SERVICES and must be protected so that legibility is guaranteed during the retention period. Any further legal obligations regarding documentation and archiving remain unaffected hereby.

10. Acceptance of goods / incoming inspection at ZEISS

On the arrival of the GOODS and SERVICES, ZEISS will only check whether they correspond to the quantity and type ordered, whether there is visible external transport damage on the

packaging or whether there are visible external defects. ZEISS will also normally undertake random checks of the quality documents / certificates which accompany the delivery.

ZEISS reserves the right to conduct additional checks and tests on a case by case basis.

The SUPPLIER must orient its Quality Management system and Quality Assurance measures to this reduced testing and inspection of incoming goods.

ZEISS will inform the SUPPLIER in writing about defects on the GOODS and SERVICES which were delivered as soon as they are identified during the regular course of business. In this respect, the SUPPLIER will waive the objection of delay in lodging a complaint.

11. Special release prior to the delivery of the GOODS and SERVICES to ZEISS

If the SUPPLIER is unable to supply the GOODS and SERVICES as agreed in accordance with the contract by reason of non-conformities identified prior to delivery and if the deviations cannot be rectified by special efforts and emergency measures before the agreed delivery date, in truly exceptional cases the SUPPLIER may request approval for the delivery of non-conforming GOODS and SERVICES by means of an application for special release.

Nevertheless, the urgency of the supply situation must always be first clarified with the person at ZEISS who placed the order and efforts made to rectify the deviations by reconditioning or supplementary work.

The causes of the deviations which were identified must be analyzed immediately and suitable corrective action taken which will permanently prevent the recurrence of the deviations.

The application for special release must be made in writing using the ZEISS form and sent to the person at ZEISS who placed the order. The application must always contain a detailed description of the deviation, the cause which was identified, the corrective actions taken and the planned time of implementation.

The Quality Management, Technical Development and other areas of ZEISS will assess the application for special release with regard to the potential effects and risks of the deviation.

At the conclusion of the assessment ZEISS will inform the SUPPLIER about the decision taken with regard to 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 but with a reduction in the purchase price
3. Refusal of the defective delivery and refusal of the special release

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

All deliveries based on a special release must be clearly and unambiguously marked. A copy of the special release signed by ZEISS must be attached to the GOODS and SERVICES when they are delivered.

Any declaration by ZEISS to waive the assertion of warranty claims regarding the defective GOODS and SERVICES as part of the special release does not constitute a waiver of the assertion of warranty claims based on other defects in the GOODS and SERVICES.

12. Rejections / complaints

In the event of rejections, these will be processed by the SUPPLIER in a prescribed, structured method of resolving the problem; this method will ensure that the defects are rectified in a sustainable and permanent manner. ZEISS will decide on a case by case basis which of the following methods will be used:

- SUPPLIER'S comments (E-Mail)
- 5D report
- 8D report

The SUPPLIER must reply and provide a report promptly within the time-limits and conditions set by ZEISS.

13. Supplier Assessment

ZEISS regularly conducts supplier assessments based on the GOODS and SERVICES supplied by the SUPPLIER; amongst other things, these assessments are also considered when selecting suppliers and when considering further collaboration with the SUPPLIER. The supplier assessment is also the basis for the joint determination of quality objectives with the SUPPLIER in order to achieve continuous improvement. If these objectives are not achieved and depending on the case in point, a supplier development program may be agreed between the PARTIES in order to ensure that the SUPPLIER'S planned supply performance is achieved; alternatively the volume of deliveries may be reduced or the SUPPLIER may even be black-listed.

The assessment is based on supplier-related logistics and quality data (HARD FACTS). In the case of suppliers with the status of "Managed Supplier" or "Strategic Partner", criteria such as QM systems, health and safety/environmental management systems, logistics, price level, technology and commercial requirements (SOFT FACTS) will also be assessed. Compliance with the provisions agreed in this QAA will also be taken into consideration in the supplier assessment.

14. Audits

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

The audit may be conducted as a system, process, product or mixed audit. Audits will be conducted in every case after giving prior notice and by agreement. If necessary, the SUPPLIER will enable audits to be conducted at short notice if so requested by ZEISS. The SUPPLIER will grant ZEISS and, in so far as is necessary, customers of ZEISS access to all manufacturing sites, testing laboratories, warehouses and adjacent areas and will also allow ZEISS sight of all documents relevant to the audit as well as access to tools, testing equipment and devices. Necessary and reasonable restrictions by the SUPPLIER to protect its company secrets will be accepted during this process.

If quality problems occur which are caused by a sub-contractor, the SUPPLIER will, if necessary, procure the option for ZEISS and, in so far as necessary ZEISS’ customer, to audit this sub-contractor.

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 will inform the SUPPLIER of the findings of the audit. If, in the opinion of ZEISS, corrective measures 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 PARTIES as part of the audit will be subject to confidentiality according to the provisions agreed between the PARTIES.

15. Duration and termination of the agreement

This QAA will become effective upon the signature of the PARTIES TO THE CONTRACT and will apply to all GOODS AND SERVICES supplied by the SUPPLIER to ZEISS after the effective date of this Agreement.

Each PARTY TO THE CONTRACT may terminate this QAA by giving 6 months' notice at the end of any month.

16. Final provisions

16.1. Written form

Amendments of and/or additions to this QAA will only be valid if they are made in writing and signed by two persons for ZEISS and one duly authorized person for the SUPPLIER. Where this QAA stipulates that notices must be submitted and declarations given in writing, such written form may not be substituted by the electronic form; in all other cases, text form shall be sufficient.

16.2. Severability clause

The ineffectiveness or invalidity of one or more provisions of this QAA shall not lead to its invalidity overall. The PARTIES will replace ineffective or invalid provisions through such effective provisions which 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. Applicable 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 (CISG) of April 11, 1980 does not apply.

16.4. Jurisdiction

For both PARTIES the jurisdiction for all disputes arising from and in connection with this QAA will be the legal domicile of ZEISS only. At its discretion, ZEISS may, however, bring an action before the courts at the SUPPLIER'S place of jurisdiction.

16.5. Other Applicable Documents

Attachment A: Particular Quality Assurance provisions

17. Signatures

This QAA is prepared in two identical originals of which each party obtains an original. The copies are only validly signed if all signatures have been applied.

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

Attachment A: Particular Quality Assurance provisions

No additional regulations were agreed on the general part of the QSV.

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