



Quality Assurance Agreement (QAA)

between

Carl Zeiss Meditec <AG>
<Goeschwitzer Strasse 51-52>
<D-07745 Jena>
<Germany>

hereafter referred to as "CUSTOMER"

and

<Name of Supplier>
<Address supplier>
<Country supplier>

hereafter referred to as "SUPPLIER"

CUSTOMER and SUPPLIER also known as
"CONTRACTUAL PARTNERS"

Abbreviation: _____ (Date) (Customer)	Abbreviation: _____ (Date) (Supplier)
Version: <...> Template: CZM-6-41-00-03-TP-E	valid from: <Date> Page 1 of 18



Contents

Preamble..... 3

1. Scope 3

2. Data, requirements and documentation 3

 2.1. Data 3

 2.2. Terms 5

 2.3. Documentation 5

 2.4. Software / Firmware development / modification 6

 2.4.1. Software Development Plan 6

 2.4.2. Requirement, Architecture 6

 2.4.3. Verification 7

 2.4.4. Software release 7

 2.4.5. Software Configuration Management 7

 2.4.6. Software maintenance process 8

 2.4.7. Problem Resolution Process 8

3. Quality Management..... 8

 3.1. Quality Management of SUPPLIER 8

 3.2. Cooperation with subcontractors 9

4. Quality Monitoring 9

5. Risk Evaluation 10

6. Quality Assurance 10

 6.1. General Requirements 10

 6.2. Evaluation of feasibility 11

 6.3. Production release 11

 6.4. Product/Process Audit..... 12

 6.5. Initial sample testing..... 12

 6.6. Incoming Goods Inspection..... 13

 6.7. Quality Assurance in the Production Phase..... 13

 6.8. Test Certificates 13

 6.9. Testing by the Customer 14

 6.10. Packaging..... 14

 6.11. Labelling and Traceability 14

7. Supplier Evaluation and Audits..... 15

 7.1. Supplier Evaluation 15

 7.2. Audits 15

8. Complaints 16

9. Contacts..... 16

10. Product liability 17

11. Duration of Agreement and Termination 17

12. Closing Provisions 18

Abbreviation: _____		Abbreviation: _____	
(Date)	(Customer)	(Date)	(Supplier)
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 2 of 18



Preamble

This Quality Assurance Agreement (hereinafter referred to as QAA) shall designate and regulate all scheduled procedures between the CONTRACTUAL PARTNERS and is intended to ensure the quality of products, goods and services.

It specifies the minimum requirements of the management system of the contractual partners. In this QAA, the CUSTOMER comprehensively defines the requirements and duties of the PARTIES to assure the specified quality that also affects the contractual terms and regulations.

1. Scope

This agreement shall apply to the delivery of all products, goods and services by the supplier to the customer, including those to be included in the product scope in the future cooperation.

The regulations of this QAA apply as appendix to frame contract, frame purchasing contract or frame development contract, as agreed between the CONTRACTUAL PARTNERS or as appendix to the general Purchasing Terms & Conditions as applicable. In case of conflicts, the following order of precedence applies:

1. Frame contract resp. frame purchasing contract
2. Frame development contract
3. This QAA including any appendices as applicable
4. General purchasing terms and conditions of the CUSTOMER

The QAA shall apply for all products, goods and services provided by the SUPPLIER to the CUSTOMER.

2. Data, requirements and documentation

2.1. Data

The contractual basis for the determination of quality and compliance with the specifications, functionalities and characteristics of the purchased products and services shall be the technical data on which the order was based, such as drawings, technical specifications, requirement specification (RS), functional specification (FS), standards, contract-specific

Abbreviation: _____ <small>(Date) (Customer)</small>		Abbreviation: _____ <small>(Date) (Supplier)</small>	
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 3 of 18



requirements e.g. testing or process requirements and other contractual provisions.

This shall also apply to software products and software installation of which the scope of delivery (e.g. transfer of source code, rights of use for programs documentation etc.) is defined in procurement specifications and development contracts.

The SUPPLIER shall receive from the CUSTOMER the latest revised version of the technical data and shall ensure by means of appropriate internal procedures relating to subcontractors that production will take place only in accordance with the currently valid revision.

Any changes the SUPPLIER may wish to make to specifications, design, manufacturing process or to the agreed quality management system must be approved in advanced in writing by the CUSTOMER.

The SUPPLIER is furthermore obliged to obtain the written agreement of the CUSTOMER before changing any processes and/or processes requiring validation that may have an impact on quality and reliability of the CUSTOMER's products; and to provide records demonstrating quality that are to be approved by the CUSTOMER.

The following changes require approval by the CUSTOMER as a matter of principle:

- Changes to specification and other terms stipulated in the purchasing documents
- Any change to the state of construction (including any use of substitute components in case of obsolescence)
- Changes affecting product life
- Changes affecting environmental safety
- Changes of spare parts related to the product
- Changes of test and verification plans
- Changes or re-location of production facilities
- Change of sub-suppliers
- Relocation of the production of entire units to sub-suppliers (third parties)
- Changes that relate to packaging, handling, installation or installation requirements
- Changes to software and firmware
- Changes to defined operating conditions
- Changes affecting production or maintenance or related documentation
- Changes of production processes or production equipment
- Changes to the quality management system certificates of the SUPPLIER, e.g. expiry of ISO 9001 certificate.

If the SUPPLIER is not able or is not sufficiently able to evaluate the impact on specification, functionalities and reliability of the CUSTOMER's products, the SUPPLIER shall obtain a written approval from the CUSTOMER as a general principle.

Should the SUPPLIER consider new or revised regulatory requirements to mandate changes to agreed specifications, he shall immediately inform the CUSTOMER.

Abbreviation: _____ (Date) (Customer)	Abbreviation: _____ (Date) (Supplier)
Version: <...> Template: CZM-6-41-00-03-TP-E	valid from: <Date> Page 4 of 18



2.2. Terms

(1) As the CUSTOMER distributes its products globally, the SUPPLIER must apply all relevant national and international legislative requirements and guidelines (current issue) required for the development, construction, manufacture and testing of the delivery items or services has to obtain the relevant certificates. The SUPPLIER has to inform the CUSTOMER immediately about any changes regarding the status of its certificates or when he cannot observe the applicable national and international legislative requirements and guidelines.

(2) This also includes all applicable laws and directives relating to environmental protection and employee safety.

(3) The SUPPLIER shall, at the request of the CUSTOMER, provide product-relevant proof that the products to be delivered comply with all legal requirements.

Where it has been agreed that the product or its components will comply with technical guidelines and standards such as CE, IEC or UL specifications, the SUPPLIER shall provide series or batch number-related proof in terms of DHR documentation.(DHR: Device History Record).

The SUPPLIER shall comply with all essential requirements in accordance with state-of-the-art technology and science, safety guidelines and agreed technical data when making deliveries.

2.3. Documentation

(1) Where the SUPPLIER has been charged with the development of a product, it shall produce a functional specification (FS) based on the requirements specification / functional specification (FS) and shall implement such development in accordance with its development process.

(2) When development is complete the SUPPLIER shall submit documentation pertaining to the origin of the product (DHF: Design History File) and documentation concerning the production requirements of the product (DMR: Device Master Record, e.g. drawings, test schedules, parts lists etc.)

(3) The details shall be regularized in the development contract.

(4) Additional requirements for delivery of software see section 2.4.

The SUPPLIER shall document the manufacture of each product or service. (DHR: Device History Record, e.g. work in progress documentation, inspection and test records, test protocols, certificates etc.). These documents shall include proof of procurement and of manufacturing and testing stages for each product manufactured in relation to its series or batch number and shall include test results in the testing protocols.

Abbreviation: _____ <small>(Date) (Customer)</small>		Abbreviation: _____ <small>(Date) (Supplier)</small>	
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 5 of 18



All changes as defined in chapter 2.1 to the product / process shall be documented.

All documentation relating to development, production and procurement processes shall be held for a minimum of 15 years, shall be made available to the CUSTOMER upon request and in the event of the acquisition of the SUPPLIER shall be handed on to its successor for safe keeping. Upon the expiry of this period and on termination of the contract, the documents shall be offered to the CUSTOMER for its further use.

2.4. Software / Firmware development / modification

2.4.1. Software Development Plan

(1) Software life cycle model / processes

The software development plan shall address the life cycle model and processes used in the development.

(2) Deliverables

The software development plan shall address the deliverables (software artefacts as well as documentation) of the activities.

(3) Responsibilities

The software development plan shall address the responsible persons for performing the organization of the team, implementation of the software, verification activities and configuration management.

(4) Traceability

The software development plan shall address the traceability between customer requirements, system requirements, software requirements, risk evaluation measures (FMEA) and system verification.

Note: Customer requirements means the requirements agreed upon between CUSTOMER and the SUPPLIER.

(5) Verification

The software development plan shall plan all deliverables requiring verification, verification tasks for each life cycle activity and acceptance criteria for verification.

Problem resolution process

The plan shall address the process handling problems detected in software products, deliverables and activities.

2.4.2. Requirement, Architecture

The documented software requirements shall be traceable to system requirements and system test cases. The Architecture of the software (including OTS “Off-the shelf” / SOUP “Software of unknown (or uncertain) pedigree (or provenance)” items) shall be described and verified.

Abbreviation: _____ (Date) (Customer)	Abbreviation: _____ (Date) (Supplier)
Version: <...> Template: CZM-6-41-00-03-TP-E	valid from: <Date> Page 6 of 18



2.4.3. Verification

- (1) The verification activities shall be performed based on documented and released test specifications containing a set of tests (input stimuli, expected outcomes and pass/fail criteria).
- (2) The verification activities shall be conducted on different levels depending on the architecture (unit, integration, system level). Integration test may be a part of system test.
- (3) In order to support the repeatability the documentation of test shall include:
 - Test result (pass/fail and a list of anomalies)
 - Unique Identification of test object:
 - Version of software under test
 - relevant hardware and software test configurations
 - version of test tools
 - Identity of the person responsible for executing the test and recording the test results with date tested
- (4) Validation of tools
Tools with potential influence on quality shall be validated for their intended use.

2.4.4. Software release

- (1) The supplier shall ensure that all software requirements have been tested or otherwise verified and the test results meet the required pass/fail criteria before releasing a software.
- (2) The supplier shall establish and evaluate a list of all known residual anomalies.
- (3) The supplier shall document the version of the software that is being released.
- (4) The supplier shall archive the software and configuration items and the documentation and shall provide the deliverables to CZM.
- (5) The supplier shall establish procedures to ensure that the released software can be reliably delivered to the point of use without corruption or unauthorized change.

2.4.5. Software Configuration Management

- (1) Description
The software configuration management shall address a description (e.g. version, storage) of SW Items, Off the Shelf- Software (OTS / SOUP) and SW tools used for development.
Note:
 - Archiving the source code files as well as the binaries
 - Archiving documentation
 - Tools used for development

Abbreviation: _____ (Date) (Customer)	Abbreviation: _____ (Date) (Supplier)
Version: <...> Template: CZM-6-41-00-03-TP-E	valid from: <Date> Page 7 of 18



- (2) Activities and tasks
The supplier shall document the versioning, build management, virtual build machine.
- (3) The configuration items shall be taken under documented configuration management control at least before starting their verification activities.

2.4.6. Software maintenance process

- (1) Any changes in the software artefacts must be approved in writing by the customer in advance.
- (2) All changes in the software (Bugfix, changes of hardware components) shall be performed regarding this QAA. Tailoring of this process is possible after agreement by customer.

2.4.7. Problem Resolution Process

Problems can be defects in the software itself as well as in the documentation:

- Problems reported by customer
 - The supplier shall investigate the problem and identify the causes and evaluate effects to the component.
 - Problems found by supplier
- (1) The supplier shall notify the problem to customer. The supplier shall investigate the problem and identify the causes and evaluate effects to the component.
 - (2) The supplier shall use the defined change control process to implement the changes implemented due to problem resolution process.
 - (3) The supplier shall verify the resolution to determine whether the problem is fixed and no side effects have been introduced.

3. Quality Management

3.1. Quality Management of SUPPLIER

(1) The SUPPLIER shall undertake the timely implementation and maintenance of an effective, certified management system for quality, environment and occupational safety covering all aspects of its company in accordance with the current valid international standards and guidelines. This management system shall at least be based on the

Abbreviation: _____ <small>(Date)</small>	_____ <small>(Customer)</small>	Abbreviation: _____ <small>(Date)</small>	_____ <small>(Supplier)</small>
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 8 of 18



International Standard ISO 9001:2015 or on a system which at least satisfies all the requirements included in the aforementioned standard

(2) The SUPPLIER shall maintain an environment management system that complies with local, regional and national applicable standards and regulations, including requirements related to consumption of resources (water, air, energy, resources etc.), including requirements for recycling and documentation for disposal of waste and products (e.g. as to ISO14001, IMDS, REACH).

(3) Where a product delivered by the SUPPLIER constitutes a medical device in terms of Medical Device Legislation (MPG or MDR), certification in compliance with DIN EN ISO 13485:2016 is compulsory.

The SUPPLIER shall provide evidence of the requirements defined in this chapter in the form of a certificate. The SUPPLIER shall inform the CUSTOMER promptly and without necessity of request of each amendment, adjournment or suspension of the certificate.

If, as to the SUPPLIER, changes to standards and regulations may require a change to the agreed specifications, he shall inform the customer in advance in writing, allowing the CUSTOMER to comment within a reasonable period of time. In such case, the CUSTOMER and the SUPPLIER shall come to a mutual agreement concerning further procedure.

3.2. Cooperation with subcontractors

The SUPPLIER shall require his subcontractor to comply with the obligations that he has accepted itself in this agreement with the CUSTOMER.

Upon request of the CUSTOMER, the SUPPLIER shall provide documented evidence that the supplier has satisfied itself as to the effectiveness of the QM system of his subcontractor. Moreover, the CUSTOMER can request the SUPPLIER to provide test and quality reports from his sub-supplier.

4. Quality Monitoring

The SUPPLIER shall carry out quality monitoring for products in accordance with his internal QM flow charts Extent and scope of the applied QM plan shall result from the risk evaluation of the SUPPLIER.

Prior to implementation in production, he shall inform the CUSTOMER in writing of any planned changes to the processes related to the conditions listed under 2.1. Based on this information, any re-sampling volumes which may become necessary shall be determined.

The SUPPLIER shall ensure that products that internal controls have identified as non-conforming shall not be delivered to CUSTOMER.

Abbreviation: _____ (Date) (Customer)	Abbreviation: _____ (Date) (Supplier)
Version: <...> Template: CZM-6-41-00-03-TP-E	valid from: <Date> Page 9 of 18



Products that have been reworked or repaired shall be subject to the same requirements as new products in terms of quality and function. Repaired products shall be labelled as repaired products and shall be delivered separated from serial products.

The measures referred to above require written approval by the CUSTOMER.

5. Risk Evaluation

The SUPPLIER shall carry out a risk evaluation of the product to be delivered and of the manufacturing process. The risk evaluation is a part of the documentation the SUPPLIER is obliged to maintain; for archiving and retention, the defined retention periods apply.

Both Design- and Process FMEA shall be required as risk analysis where a SUPPLIER delivers products manufactured in accordance with his own construction drawings. Otherwise, a process FMEA shall be undertaken.

The SUPPLIER shall maintain a procedure to identify the hazards and evaluate the risks associated with its delivered products throughout their entire lifecycle. Compliance with this procedure shall be regularly monitored and adjusted if necessary.

Where the SUPPLIER identifies risks that are likely to affect the CUSTOMER's product, it shall inform the CUSTOMER promptly and in writing. This shall also apply to risks which have been identified or which have arisen in similar or similarly constructed products. Decisions on any necessary corrective actions and information related to products in the field / recalls / notification of authorities shall rest with the CUSTOMER.

The SUPPLIER shall maintain a system capturing failures / non-conformities as a means to ascertain weaknesses of products or processes. The system shall be used to define all necessary corrective and preventive actions (CAPA=Corrective and Preventive Action).

6. Quality Assurance

6.1. General Requirements

The SUPPLIER shall cover with its quality testing all processes from incoming quality control throughout the entire manufacturing process up to dispatching of the finished delivery items, in order to ensure compliance with all quality requirements.

The SUPPLIER shall ensure that products obtained from his subcontractors fulfil the agreed quality requirements. The requirements defined in these agreement shall be transferred to his subcontractors.

Abbreviation: _____ (Date) (Customer)		Abbreviation: _____ (Date) (Supplier)	
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 10 of 18



The CUSTOMER reserves the right to observe all processes and tests required for the delivery items in the manufacturing plant. The SUPPLIER will grant the CUSTOMER all access rights and information.

The SUPPLIER shall conduct process capability tests on all features that, as to the FMEA, affect functionality or safety or that determine the quality. On request, process capability indices (Cp / Cpk) shall be agreed in consultation between the supplier and customer.

The SUPPLIER shall ensure that adequate measuring and test equipment for monitoring all characteristics defined in the specifications are at his disposal and that these are applied.

Capability analysis shall be carried out on all processes, methods and plant employed, including software and measuring and testing equipment, e.g. according to DIN 55350 Part13, DIN 1319 Parts 3 and 4.

If the CUSTOMER provides test equipment or test software, the SUPPLIER shall treat this equipment with appropriate care and as its own testing equipment. The equipment shall be managed in the SUPPLIER's system established for managing equipment and calibration control. Records on calibration are to be archived and are to be made available to the CUSTOMER on request.

The SUPPLIER shall periodically and systematically monitor and control test equipment and reference standards as to written procedures on managing calibration. All records on calibration control shall be archived and are to be provided to the CUSTOMER upon request.

6.2. Evaluation of feasibility

If new or changed products or services are requested for quote, the SUPPLIER is committed to assess feasibility in regards to engineering, logistics and quality requirements (quality goals), based on the provided specifications and referenced documents.

The assessment of manufacturability should be provided to the CUSTOMER together with the offer. The assessment of manufacturability is also required for changes (see change management).

Offers from SUPPLIER to CUSTOMER require a positive feasibility study (complete fulfilment of the requirements). If feasibility is not confirmed in all aspects a clarification of the problem with the CUSTOMER is required prior to offering.

6.3. Production release

Production release shall take place only after approval has been given by the CUSTOMER and produced items shall satisfy the approved initial sample in terms of construction, materials and processes.

(1) Production release shall be required

Abbreviation: _____ <small>(Date) (Customer)</small>		Abbreviation: _____ <small>(Date) (Supplier)</small>	
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 11 of 18



- for first delivery,
- after any change to specification as specified in the order
- for deliveries at greater intervals (more than 18 months),
- if any changes to the production process and relocation of production has been made.

(2) Production release shall be approved by the quality management team of the CUSTOMER:

- (3) Production release shall be based on an assessment of
- initial sample testing and/or
 - process monitoring by the supplier (see 6.1.5) and/or
 - product / process audit report.

(4) The criteria for production release (initial sample, process monitoring, product / process audit) shall be defined in the order.

The first delivery batch following any change shall be labelled separately. Following the first delivery of the changed product, there shall be no further distribution of "former amendment status" products.

6.4. Product/Process Audit

Where series production conditions have been completely implemented or as a requirement of approval; the CUSTOMER may carry out a combined product/ process audit at the SUPPLIER's site, in order to review implementation and effectiveness of all planned quality assurance measures.

In case of a negative audit result, the CUSTOMER shall be entitled to carry a post-audit out. The CUSTOMER defines type and extent of the post-audit. The audit is passed if the SUPPLIER can prove the accompanying documentation with (its) introduced measures and effectiveness.

The costs engendered by the SUPPLIER for the purpose of post-audit (by the customer), shall covered by the SUPPLIER.

6.5. Initial sample testing

(1) If the CUSTOMER commissioned initial sample, the SUPPLIER shall produce under series conditions and with series equipment. The initial samples has to comply with the CUSTOMER's specific requirements.

(2) Production capability shall be documented in an initial sample report together with all test features defined in the drawing/ specification.

The initial sample documentation shall include, insofar as not otherwise agreed, the following evidence:

Abbreviation: _____ <small>(Date)</small>	_____ <small>(Customer)</small>	Abbreviation: _____ <small>(Date)</small>	_____ <small>(Supplier)</small>
Version: <...>	Template: C2M-6-41-00-03-TP-E	valid from: <Date>	Page 12 of 18



- a measurement report for the number of parts specified in the order, assignable to the test chart as specified in the order
- measurement system and equipment capability, if requested
- materials certificate/acceptance test certificate
- technical data sheet
- declaration of conformity, if necessary

The CUSTOMER shall inspect the conformity of the data to the technical documentation and shall inform the SUPPLIER of his decision. CUSTOMER orders are not to be considered as positive inspection decision.

Certification of appropriate testing shall be provided for any additional specification requirements pertaining to a product to be supplied, such as lifespan, temperature tolerance, corrosion protection etc.

The results of the aforementioned tests shall be supplied with the initial sample report.

6.6. Incoming Goods Inspection

The SUPPLIER shall ensure that products obtained from his subcontractors also meet the agreed quality requirements.

The requirements contained in this agreement shall be communicated to his subcontractors.

6.7. Quality Assurance in the Production Phase

The SUPPLIER shall ensure that the products and services supplied under this agreement are free from material defects and defects of title.

Appropriate procedures such as statistical process controls (SPC) shall be put in place to monitor and regulate processes. Upon request of the CUSTOMER, the supplier has to enclose the certificate of conformity and the release certificate.

In case of the delivery of sterile products; the SUPPLIER shall coordinate validation of the sterilization process by regular re-validation in compliance with the requirements of the relevant applicable standards, to carry out this validation and to make the revalidation report available to the CUSTOMER.

Where no revalidation cycle is specified, re-validation shall be carried out regularly and at least after 2 years.

6.8. Test Certificates

Abbreviation: _____ <small>(Date) (Customer)</small>		Abbreviation: _____ <small>(Date) (Supplier)</small>	
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 13 of 18



The SUPPLIER shall maintain records of material-, end product- and in-process-inspections and of all other batch-related quality assurance procedures and shall retain these records for at least 15 years from the date of delivery to the CUSTOMER. Where so agreed with the CUSTOMER, other additional reserve samples shall be retained for the same period.

The CUSTOMER may go back on these dates after prior notification and/or in terms of product liability requirements.

6.9. Testing by the Customer

The CUSTOMER carries out an incoming goods inspection according to own appraisal.

In case of defects, which were assessed as series defects, the first pronounced complaint applies for the whole series. In case of occurrence of the same kind of defect on more than 2% of the products during or within 5 years the warranty period (serial defects), means that all products which the CUSTOMER delivered to the others have the same defect.

6.10. Packaging

As long as there are no written guidelines by the CUSTOMER, the SUPPLIER is responsible for proper packages and labelling of the delivery items for the contractually intended delivery purpose. Returnable package are generally preferred.

6.11. Labelling and Traceability

Parts and materials shall be handled and labelled throughout the manufacturing process, from receipt of goods to dispatch such that any possibility of confusion or mixing of materials/parts is excluded.

- (1) A traceability system shall be installed in case of warranty issues, in order to facilitate tracing and limitation to a particular production / delivery batch.
- (2) The SUPPLIER shall undertake to label each delivery batch clearly by designation, part number, revision status, amount, batch number/ serial number.
- (3) The additional use of an HIBC bar code shall be permitted.
- (4) Based on this labelling and in association with the internally installed data archive / traceability system and in the event of a CUSTOMER claim relating to any particular order, the SUPPLIER shall be in a position to undertake fault isolation in regard to production date, batch number where relevant, delivery amount and date of delivery.
- 5) The SUPPLIER warrants a traceability system which ensures the traceability of its components and raw material used. The SUPPLIER has to ensure that such a traceability

Abbreviation: _____ <small>(Date) (Customer)</small>		Abbreviation: _____ <small>(Date) (Supplier)</small>	
Version: <...>	Template: CZM-6-41-00-03-TP-E	valid from: <Date>	Page 14 of 18



exists at his subcontractors and that the notified body of the CUSTOMER and other authorities as well as the CUSTOMER will granted access to the information on request.

7. Supplier Evaluation and Audits

7.1. Supplier Evaluation

The quality of incoming goods and products shall be evaluated by the CUSTOMER. The SUPPLIER shall be informed of the result after the evaluation or annually.

At the request of the CUSTOMER a quality meeting should take place. A quality consultation regarding quality assessment shall take place annually between the CUSTOMER and the SUPPLIER.

In the course of this quality meetings the SUPPLIER commits itself to disclose all the quality-related documents.

7.2. Audits

The SUPPLIER shall permit the CUSTOMER to ascertain from his audits whether his Quality Assurance procedures meet the requirements of the CUSTOMER. An audit shall be announced in a timely manner.

The CUSTOMER shall inform the SUPPLIER in writing of the result of this audit. Where in the opinion of the CUSTOMER remedial procedures are necessary, the SUPPLIER shall undertake promptly to prepare a plan of action, to implement it at a due date and to inform the CUSTOMER of this.

Audits by other customers and certificates may be accredited.

The SUPPLIER shall, in relation to his deliveries, be prepared to carry out with the CUSTOMER and by agreement a joint audit of his subcontractors.

The SUPPLIER shall permit on request without notice the relevant monitoring authorities or in the case of medical devices the "notified body" responsible for the CUSTOMER to conduct an audit of the industrial premises in which products are manufactured and of the quality management procedures of the SUPPLIER and also to inspect all technical documentation relating to the product or to the quality management system. This comprises that the SUPPLIER has to ensure that the same rights are enforceable regarding his subcontractors.

Abbreviation: _____ (Date) (Customer)	Abbreviation: _____ (Date) (Supplier)
Version: <...> Template: C2M-6-41-00-03-TP-E	valid from: <Date> Page 15 of 18



8. Complaints

Where any deviations of processing are noticed as a result of assembly problems, CUSTOMER complaint or other examinations, the SUPPLIER shall be informed promptly.

The CUSTOMER shall inform the SUPPLIER in writing (by fax or e-mail) and the SUPPLIER shall respond in written to the complaint within 2 work days, specifying the necessary measures and procedures to be undertaken. If no statement from the SUPPLIER is forthcoming, the CUSTOMER shall have the right to initiate appropriate/necessary measures.

After notification of the problem, the SUPPLIER shall undertake to instigate measures to investigate the cause of the fault and to ensure that subsequent deliveries are free from error.

The SUPPLIER shall provide immediately a substitute delivery

The SUPPLIER shall undertake to analyze all deviations and to issue a statement in the form of an 8D report. The final statement shall be brought to the attention of the customer in writing within 30 days.

The CUSTOMER shall reserve the right to charge to the SUPPLIER all costs ensuing from the complaint, in accordance with the causative principle.

Furthermore, the CUSTOMER shall reserve the right to charge to the SUPPLIER an expenses allowance of 250 EUR for each authorized complaint. The CUSTOMER may provide evidence as may be required.

9. Contacts

Quality Assurance Officer / Quality Management Officer for SUPPLIER:

Name:

Department:

Tel:

Fax:

E-Mail:

Quality Assurance Officer / Quality Management Officer for CUSTOMER:

Name:

Department:

Tel:

Abbreviation: _____ (Date) (Customer)	Abbreviation: _____ (Date) (Supplier)
Version: <...> Template: C2M-6-41-00-03-TP-E	valid from: <Date> Page 16 of 18



Fax:

E-Mail:

10. Product liability

It is possible that, despite all efforts to ensure product quality, faulty products may be delivered to CUSTOMER. The SUPPLIER shall undertake to accept product liability insurance that shall be maintained for the duration of the contract and shall ensure that the liability covers a minimum of 5 Mio € for damages to persons and inventory. Moreover, the supplier shall arrange a recall insurance, covering 10 Mio €. The SUPPLIER shall provide evidence of the insurance on request of the CUSTOMER.

11. Duration of Agreement and Termination

(1) The agreement shall come into force on dd.mm.yyyy.

(2) It shall be valid for an unspecified period and may be terminated in writing after giving notice of 6 months from the end of the quarter. Orders accepted during the period of the agreement shall continue to be subject to the conditions of the agreement even after the agreement has been terminated.

Abbreviation: _____ (Date) _____ (Customer)	Abbreviation: _____ (Date) _____ (Supplier)
Version: <...> Template: CZM-6-41-00-03-TP-E	valid from: <Date> Page 17 of 18



12. Closing Provisions

(1) There shall be no verbal accessory agreements to this contract. All changes and amendments to this agreement shall be made in writing in order that they shall have legal validity. This shall also apply where the requirement in writing has been waived. Electronic communication of quality related information via supplier platform established by CUSTOMER is authorized. The SUPPLIER agrees to use the CUSTOMER supplier platform for communication.

(2) The SUPPLIER shall undertake to treat all information and knowledge acquired in connection with services rendered to the customer as confidential business information and shall not disclose it to a third party.

(3) The substantive law of the Federal Republic of Germany shall apply to the contractual relationship, but to the exclusion of the UN Convention on Contracts for the International Sale of Goods (CISG).

(4) The place of jurisdiction is Jena.

CUSTOMER:, (date).....

Carl Zeiss Meditec <AG>
<Site>

.....
(.....) (.....)

SUPPLIER:, (date).....

<Name of SUPPLIER>

.....
(.....) (.....)

Abbreviation:	Abbreviation:
(Date) (Customer)	(Date) (Supplier)
Version: <...> Template: CZM-6-41-00-03-TP-E	valid from: <Date> Page 18 of 18