**Quality ASSURANCE**

**Agreement**

**City, Date**

**Between**

**Company name**

Street name and no.

Zip-Code, City name

Country

**And**

**Supplier company name**

Street name and no.

Zip-Code, City name

Country

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# AGREEMENT PARTIES

## MANUFACTURER

The Company with its legal name and registered office as follows:

Company

Street name and no.

Zip-Code, City name

Country

hereinafter referred to as the “Company”, represented at the date of signature of this agreement in person of,

XYZ

## SUPPLIER

The Company, with its legal name and registered office as follows:

**Supplier company name**

Street name, no.

Supplier Zip-Code Supplier City name

Supplier country

hereinafter referred to as the “SUPPLIER”, represented at the date of signature of this agreement in person of,

Mr. xxx

# PREAMBLE

## MOTIVATIONS, INTENTIONS, SCOPE AND OBJECTIVES

This Quality Agreement between Company and the SUPPLIER jointly referred as the “Parties” on the delivery and regarding the development and/or manufacture of medical devices or parts of medical devices, whereas

##### The business purpose of Company is to develop, manufacture and distribute medical devices and in-vitro diagnostic products.

##### SUPPLIER is a …. (company / business objective: e.g. … a world market leader in the manufacture of precision parts and subassemblies and is specialized …)

# PRELIMINARY NOTE

#### LIABILITY TO REQUIREMENTS

The products covered by this agreement are designed to be placed on the market by Company [Firma]as medical devices within Switzerland, the European Community as well as within other territories. Therefore, they are liable to the requirements of:

###### the Council Directive 93/42/EEC concerning medical devices (MDD) as amended by Directive 2007/47/EC,

###### the Council Directive 98/79EC on in vitro diagnostic medical devices (IVDD)

###### the Medical Devices Regulation 2017/745 concerning medical devices (MDR),

###### the Regulation 2017/746 on in vitro diagnostic medical devices (IVDR),

###### the Swiss Medical Devices Ordinance (MepV; 812.213), of 17 October 2001 (status on 01. June 2019) and

###### United States CFR Title 21

#### APPLICATION TO PURCHASING ORDERS

The terms of this agreement apply to any order of Company based on this agreement.

#### ASSIGNMENTS OF RIGHTS AND DUTIES TO THE PARTIES

Subject of this agreement is the assignment of rights and duties of Company and SUPPLIER arising from the requirements of the applicable regulations and directives with regard to the delivery of products (hereafter called products under agreement) to Company or respectively a third party referred to by Company. The products under agreement are listed in the current version (revision) of the Attachment(s) to this agreement.

Each particular product under agreement is specified according to the requirements of the Swiss Medical Device Ordinance, the applicable regulation or directive and to the applied technical standards applicable at the time of delivery, and according to requirements additionally defined.

#### EXCLUSION COMMERCIAL ISSUES

The administration of commercial issues (such as price determination, exclusiveness etc.), aspects of the commercial law, especially regulations about liability, warranty, guarantee etc. are not subject of this agreement. Arrangements of this kind have to be determined and agreed in a purchasing agreement.

If the purchasing agreement and the quality agreement contradict each other in quality-relevant topics, the quality agreement prevails.

# QUALITY ASSURANCE

#### EXECUTION OF PURCHASING ORDERS

SUPPLIER will develop and/or manufacture the products according to the purchasing order, the purchasing specifications and this quality assurance agreement.

#### SUPPLIER’S OBLIGATIONS ON QUALITY MANAGEMENT SYSTEM

SUPPLIER is obliged to apply and maintain a documented quality management system according to EN ISO 13485 during the development and/or manufacture / generation of the products under agreement. Company has to be informed unsolicited and immediately about any amendment to the required certification status (changes in the scope of the certificate, withdrawal of the certificate, re-issuing and/or re-appointment of the certificate).

The SUPPLIER maintains a risk management system to provide proof of compliance with the requirements under the current applicable version of EN ISO 13485 and EN ISO 14971. Both parties agree to keep the risk management file up to date. The SUPPLIER agrees to update the process risk assessment in case of changes of the regulatory requirements, changes of the process, new risks identified and market feedback. Company will receive a copy of the documents relevant to the products under agreement for its risk management file.

#### SUPPLIER’S PURCHASES AND SUB-CONTRACTING

Should SUPPLIER purchase resources or testing equipment, software, services, material or components or other by sub-contractors – may this be for development, fabrication or for quality assurance purposes – does it by agreement need to include these in its quality management system or it needs to ensure the quality of the sub-contracted items itself. It is SUPPLIER’s responsibility to ensure that the subcontractor also adheres in its function to the defined specifications of the respective product under agreement. This applies explicitly to the requirements of the handling of documents and records as well as for the requirements of the specified certification if applicable. Any deviation from the requirements needs to be clarified with Company and agreed upon in writing.

#### SUPPLIERS OBLIGATIONS ON CONTROL OF RAW MATERIAL

The Supplier shall perform quality control tests and assays on raw materials in accordance with the purchasing specifications, and shall have sole responsibility for accepting or rejecting any non-conforming or defective raw materials in accordance with the Supplier’s quality control procedures.

#### SUPPLIER’S OBLIGATIONS TO DELIVER ACCORDING SPECIFICATIONS

SUPPLIER is obliged to deliver the products under agreement according to the versions of the listed specification documents (e.g. requirements specifications, drawings, work- and testing instructions etc.) which have been defined, mutually agreed and released in the purchasing specifications.

#### SUPPLIER’S OBLIGATIONS TO USE CALIBRATED MONITORING AND MEASURING EQUIPMENT

SUPPLIER is obliged to use calibrated monitoring and measuring equipment. The respective equipment that is used for a specific test, regardless of whether it is for incoming inspection, development, in-process control or release testing, shall be mentioned in corresponding test reports and/or in the production record (unambiguous identification number is sufficient).

#### SUPPLIER’S TO INFORM BEFORE CHANGES

SUPPLIER is obliged to inform Company in writing in good time before making any changes to the product or processes or materials under agreement; Company reserves the right to reject these changes.

#### PROCESS VALIDATIONS

The SUPPLIER agrees to validate the relevant processes required for the processing of the product (including computer systems, if applicable). For standard processes of the SUPPLIER, the SUPPLIER will perform process validations according to their own quality management system and processes. SUPPLIER agrees to provide Company with a copy of the relevant process validation reports on request.

Specific validations for products of Company are agreed upon between the parties in writing and performed according to a jointly defined process validation plan, including validation date and technical requirements. The revalidation intervals and scope are agreed upon between the parties in writing. The SUPPLIER agrees to provide Company with a copy of the specific process validation reports.

#### ENVIRONMENTAL CONDITIONS

The product under agreement (including raw material components and other, as applicable) shall be manufactured and stored according to the environmental conditions defined in the specification. Such environment, including but not limited to clean rooms and storage area) shall be qualified, maintained and inspected regularly. Records shall be generated and archived according to Supplier’s internal quality management system.

#### EMPLOYEE TRAINING

Permanent and temporary employees involved in the development and/or manufacturing, inspection, handling, storage, distribution etc. of the product under agreement shall be trained according to Supplier’s internal quality management system. Records shall be generated and archived according to Supplier’s internal quality management system.

#### IDENTIFICATION DURING DEVELOPMENT AND/ OR PRODUCTION PERIOD (TRACEABILITY)

The SUPPLIER shall document the usage of raw materials and means of production to ensure traceability of production processes at an article and batch level. All requirements will be applied thoroughly by the SUPPLIER, and Company will receive evidence thereto. During the Term, the SUPPLIER shall provide and maintain an adequate traceability system with respect to development (requirements engineering) and/or with respect to each lot (version) manufactured hereunder, in a readily accessible format and in compliance with the purchasing specifications.

Should no specific traceability of the particular products under agreement have been defined in the purchasing specifications, SUPPLIER needs to establish adequate procedures in its quality management system. This ensures that the location, time and lot/version number of the development and/or manufacture of the products under agreement can be determined, in order that in case of problems with the product and complaints the cause of error and the effect of the error can be pin-pointed.

#### DOCUMENTATION OF PROCESSES DIFFERENT TO ORIGINAL SPECIFICATIONS

If products (in order to meet their requirements) are processed in a way different from the defined specifications (e.g. in case of rework and error correction), these procedures need to be approved by Company.

The development and/or manufacturing procedures of the products differing from the defined specifications need to be documented by SUPPLIER in an adequate way.

#### DELIVERY OF NON-CONFORM PRODUCTS

Products under agreement that don’t meet the defined and agreed terms of quality assurance and purchase specification may not be delivered without prior written agreement of Company.

# COMPANY’S RIGHT TO AUDIT ON PREMISES OF SUPPLIER

#### COMPANY’S RIGHT TO CONDUCT AUDITS ON SUPPLIER’S PREMISES

In order to check the adherence to the defined specifications, Company has the right to conduct product, process and/or system audits relating to the products at an agreed time on the premises of SUPPLIER. In case important activities are outsourced by SUPPLIER, SUPPLIER shall ensure that the right to perform audits by Company is also applicable for the sub-contractor.

#### AUDITS BY COMPANY’S NOTIFIED BODY AND COMPETENT AUTHORITY

The competent authority in charge and the Notified Body (certification body) of Company are entitled to perform announced and unannounced audits at SUPPLIER in the scope demanded by the respective bodies. In case important activities are outsourced by SUPPLIER, SUPPLIER shall ensure that the right to perform announced and unannounced audits by the competent authorities and the Notified Body is also applicable for the sub-contractor.

In the event the Supplier is inspected by any regulatory authority, the Supplier shall promptly notify Company and supply Company with a copy of any written alleged violations or deficiencies relating to or affecting the development and/or manufacturing, storage and distribution of the Products under agreement. The Supplier shall use its commercially reasonable best efforts to correct any alleged violations or deficiencies.

# RECEIVING INSPECTION ON DELIVERY

#### SUPPLIER’S DUTIES ON QUALITY INSPECTIONS

SUPPLIER is responsible to conduct quality inspections according to the definitions of the purchasing specifications. SUPPLIER confirms compliance with purchasing specifications on Certificate of Conformity. Certificate of Conformity shall contain at a minimum the following information: Name of product, Article number / Reference number, Quantity, Lot number, Design History (if applicable), Device Master Record (if applicable), Device History Record (if applicable), Manufacturing date and/or expiry date, Confirmation, that the sterilization was performed according to the specification and that respective records are available (in case of sterile product(s)), Confirmation that the product meets the defined purchasing specifications, Signature release from an authorized person of the supplier.

If parts of this information is visible in other delivered standard documents, it may be omitted from the CoC.

#### COMPANY’S INSPECTION ON DELIVERIES OF PRODUCTS

Company, or a third party assigned by Company, will perform incoming inspection on the products under agreement primarily for identity, amount, externally visible defects and Certificate of Conformity.

#### ADDRESSING ABOUT DELIVERED NON-CONFORMING PRODUCTS

In the event Company rejects Products at incoming inspection due to non-conformity, Company will identify such Products and their date of delivery and provide SUPPLIER with a complaint report. Company will hold such Products for inspection by SUPPLIER or, at SUPPLIER request, shall return such Products.

If Company, or a customer to Company, discovers an alleged hidden non-conformity, Company will notify SUPPLIER promptly after discovery or notice to Company. Company will identify such Products and their date of delivery and provide SUPPLIER with a complaint report. Company will hold such Products for inspection by SUPPLIER or, at SUPPLIER request, shall return such Products.

#### REMEDY AND LIABILITY FOR NON-CONFORMITIES

In the event of a non-conformity, notified to SUPPLIER, and if such Products are unusable and remain unusable by Company, SUPPLIER shall either replace or repair such Products free of charge.

In the event the Parties should not agree as to whether or not the Products have a non-conformity, the Parties shall select an independent third party which shall test such lot or Products. The determination of the expert shall not constitute an expert opinion (Schiedsgutachten) within the meaning of article 189 of the Swiss Civil Procedure Code. The Party whose position does not prevail upon such testing shall pay the costs invoiced by such third party.

# CONTROL OF DOCUMENTS AND RECORDS

#### REQUIREMENTS DOCUMENT MAINTENANCE

In order that Company can meet its legal obligations, SUPPLIER has to fulfil its obligations in regard to the maintenance of documentation and records throughout the defined period of archiving, which is 30 years accounted from the date of the last delivery of the medical device.

Upon request by Company in writing, the SUPPLIER will transfer to Company the supporting documents prior to expiry of the agreed retention period.

#### PROVIDING DOCUMENTS AND RECORDS

On demand, Company has to be provided with any records or documents of SUPPLIER related to the product in the original version or as a copy.

# SURVEILLANCE OF DOCUMENTS BY COMPETENT AUTHORITIES AND THE NOTIFIED BODY

#### ALLOWANCE TO INSPECT BY AUTHORITIES AND/OR NOTIFIED BODY

For the purpose of official surveillance SUPPLIER allows the competent authority in charge to inspect the documents and records regarding the products under agreement to the demanded extent. This right is also granted to the Notified Body (certification body) of Company. SUPPLIER provides the competent authority and/or the Notified Body with the required documents.

#### NON-OBSTRUCTION FOR REASONS OF CORPORATE SECRECY

The surveillance of the documents by the competent authority in charge or the Notified Body may not be impeded for reasons of corporate secrecy.

# MARKET SURVEILLANCE AND EXCHANGE OF INFORMATION / DUTY OF DISCLOSURE

#### INFORMATION ABOUT PRODUCT RISKS AND FUNCTIONAL DISORDERS

The parties will inform each other within 10 working days about any product risks or functional disorders of the products under agreement getting to their knowledge.

#### REACTION ON COMPLAINTS

Any complaint notification has to be submitted to SUPPLIER by Company in due time after receipt. SUPPLIER is obliged to attend to this notification without delay, if necessary to initiate the required corrective actions and to provide Company with a statement on the reclamation incident as well as a description of the initiated actions if applicable.

SUPPLIER has to forward complaints to Company, if products of Company are affected.

#### RECALL / REPORTABLE INCIDENTS

The SUPPLIER hereby guarantees its full and prompt cooperation in clarifying reportable incidents. Company is responsible for reporting to the authorities immediately (without any delay that could not be justified). The following timelines are mandatory for the SUPPLIER in case of a reportable adverse event:

Investigation of the adverse event – 3 calendar days

Status report in case the assessment requires a deeper investigation – 15 calendar days

# TERM OF THE AGREEMENT

#### EFFECTIVE DATE, TERM AND TERMINATION

*[Term and Termination should be coupled to purchasing agreement. Please revise this paragraph in line with purchasing agreement.]*

This quality agreement shall be effective from the date of signature and is binding for any order of the products under agreement by Company placed to SUPPLIER.

The term of this Agreement shall commence on the Effective Date and, subject to earlier termination shall continue in full force and effect for three (3) years pursuant upon signature ("Initial Term"). It shall be automatically renewed for a successive three (3) year period ("Subsequent Terms") unless either Party terminates this Agreement by twelve (12) months' written notice to the other Party prior to the expiration of the Initial Term or any Subsequent Term, as applicable. Twelve (12) months before expiration of this Agreement, the Parties shall undertake activities to facilitate the phase out. Termination of this Agreement under this Section may be made with respect to the entire Agreement or a specific Product only.

#### EFFECTIV DATE FOR MODIFICATIONS OF PURCHASING SPECIFICATIONS

Modified versions of the purchasing specifications become effective at the defined time, at the earliest after documented acknowledgement of the modified revisions through both parties.

#### ARCHIVING OF DOCUMENTS

The regulations about archiving of documents, especially the retention time of documents and records have to be fulfilled according to the regulations, even if Company does no longer place any orders and/or the agreement is being terminated. Upon request by Company in writing, the SUPPLIER will transfer to Company the supporting documents prior to expiry of the agreed retention period.

#### MODIFICATION, SUPPLEMENTATION AND TERMINATION

Modification and /or supplementation of this agreement as well as the cancellation and /or termination of this agreement or of parts of this agreement need to be in writing and signed by both parties in order to become effective. Only through an explicit written agreement may this formal requirement become obsolete.

# SEVERABILITY CLAUSE

#### VALIDITY OF ARTICLES

Should regulations of this agreement or a regulation that is going to be included in the future completely or partly not be legally effective or not be practicable or lose their legal effectiveness later on, the validity of the other regulations in this agreement are not affected by this.

# RECEIPT OF THE AGREEMENT

#### CONFIRMATION OF RECEPTION

The parties of the agreement confirm receipt of one copy each of this agreement.

|  |  |
| --- | --- |
| **Place,** Date: | **Place**, Date: |
| Name, Function | Name, function |
| **Company**  Signature | **Supplier company name**  Signature |
| Name, Head QM & RA |  |
| **Company**  Signature |  |

### ATTACHMENT X to QAA COMPANY - SUPPLIER

**List of products underlying the QAA**

| **Article no.** | **Product** |
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Attachment Version X (replaces Vy from ((date))

|  |  |
| --- | --- |
| **Place,** Date: | **Place**, Date: |
| Name, Function | Name, Function |
| **Company**  Signature | **Supplier company name**  Signature |
| Name, Function |  |
| **Company**  Signature |  |