Quality Assurance Agreement

between

GREIPL GmbH
Brunnwiesen 38
94481 Grafenau

- hereinafter referred to as **"Client"**-

and

Mustermann GmbH
Musterstraße 1
95858 Musterstadt

-hereinafter referred to as **"Contractor"**-

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Preamble

This agreement defines the Client's quality requirements for the purchase of products from the Contractor. The requirements are based on the regulations of the respectively valid EN ISO 9001 or, if applicable, EN ISO 13485.

This agreement describes the Client's demands on the Contractor's quality assurance system as well as the obligations to be complied with by the Contractor with regard to the manufacture, testing and delivery of products manufactured or procured for the Client.

The term "quality" used in this context refers to the full conformity of the parts and materials to the requirements arising from the documents handed over and the agreements made by the Client.

It is the Contractor's responsibility to communicate these requirements to its suppliers and to regulate compliance with the provisions of this document.

The Client requires appropriate measures to be taken to achieve total customer satisfaction and the lowest total costs as well as continuous improvement measures to achieve the zero-error goal.

1. Quality assurance

The Contractor bears sole responsibility for the quality of the products manufactured or delivered for the customer. The coordination of the quality assurance measures with the Client does not release the Contractor from its responsibility for the quality of its products.

2. Protection of the environment and occupational health and safety

For each delivery, the requirements of the "Directive on the Prohibition and Declaration of Ingredients", (RoHS, REACH), each in the currently valid version, must be complied with.

Insofar as the Contractor carries out work on the Client's premises, it shall comply with the relevant applicable work and safety regulations and shall comply with the Client's instructions on conduct on the premises.

3. Evaluation of product requirements

The Contractor steers all technical documents and checks them with the aim of ensuring that they meet the respective requirements and accompanying documents of the purchase order.
The Contractor is obliged to examine all documents, drawings and specifications for errors or ambiguities. The work sequence plans and inspection plans shall be made available to the Client on request. This check must be carried out before the start of production.

If, after checking the information sent, the Contractor determines that it is incomplete, contradictory or impracticable for the Contractor from a technical or commercial point of view for the provision of the service, the Contractor shall contact the Client immediately. This feedback must be given in text form no later than three working days after receipt of the data by the Contractor.

4. Manufacturing, measuring and test equipment

The Contractor is responsible for ensuring that the specified quality requirements are met with the appropriate manufacturing, measuring and test equipment.

5. Monitoring and measurement of the product

The Contractor must satisfy itself of compliance with the quality requirements before shipping the products to the Client.

The Client reserves the right to subject any deliveries to an inspection/check with the aim of checking to what extent there is conformity with all Client documents, drawings and specifications as part of the delivery order. This also includes service life, material and construction checks. In exceptional cases, the inspection can be carried out at the Contractor's premises, wherein all relevant documents and test equipment can be made available to the Client on request.

6. Initial sampling

If the Client requests initial sampling on the order, the Contractor shall attach the corresponding documents to the shipment in the form required by the customer. Series delivery may then only take place after approval of the initial samples. A change in the production process after the initial sample approval requires a new initial sample inspection, which must be carried out at the expense of the Contractor. (Further in section 7)

7. Product and process changes

The Contractor further undertakes to obtain the consent of the Client before changing process-relevant processes and/or processes requiring validation and to provide proofs of quality proof to be agreed in this case, e.g. in the event of:

- a change of materials (also in the case of subsuppliers)
- a change of process-relevant subsuppliers
- a change in the manufacturing process
- a change of manufacturing facilities
- a change of test procedures, test equipment
- relocation of manufacturing sites

8. Production facility

The production facilities for the production parts delivered to the Client shall be communicated to the Client in writing by the Contractor.

9. Requirements for logistical quality

10. Marking of goods

The Contractor shall mark the products in the form agreed with the Client. The marking must be clearly and visibly affixed to the delivered goods. Each shipping unit must be marked at least with information on the consignee, delivery note number, order number, material number, quantity, sender and date of manufacture.

If traceability is required for a product, further information is absolutely necessary, even on every smallest packaging unit. This information as well as the associated label shall be coordinated and agreed in advance between the Client and the Contractor.

11. Traceability labelling

For products for which the Client requires traceability, the Contractor must be able to identify the delivered material and, in the event of quality deviations, to isolate all affected products. All materials and process steps must be traceable. The data of the product-relevant manufacturing and logistics processes must be documented and stored by the Contractor in a suitable traceability system. Traceability records must be submitted within 2 working days of being requested by the Client.

11.1 Packaging

The packaging materials must comply with the statutory environmental regulations applicable in the EU. The packaging must be chosen in such a way that no damage or reduction in quality of the products is to be expected during transport, storage and handling.

ESD and moisture-sensitive components must be packaged and labelled in accordance with the following internationally valid standards: IEC 61340-5-3 and IPC/JEDEC J-STD-033 in the respectively valid editions.

12. Retention periods

The retention period for documents that are subject to retention (e.g. applicable test and production documents, approved deviations, test sample quantity, material specification, measured values, test data and all data required for traceability) is based on the legal regulations, but is at least 10 years.

13. Quality goal

The Contractor is obligated to the zero-defect goal and communicates it both internally and to its own contractors. If error-free delivery is not guaranteed, the Contractor shall agree with the Client on interim objectives (temporary upper limits for defect rates). The contractor shall work continuously on measures to improve and achieve the zero-defect goal.

Falling below agreed upper limits does not release the Contractor from its obligation to process all complaints. If the agreed upper limits are exceeded, the Contractor shall immediately initiate effective improvement measures at its own expense and inform the Customer of the progress on an ongoing basis. The Contractor's liability for all defective deliveries shall remain unaffected by agreed upper limits.
Quality discussions with main topics such as preventive quality assurance, evaluation of the exchanged quality data, defect discussion, discussion of current topics, etc. shall take place at the request of a contractual partner. In the event of an escalation, the Contractor undertakes to hold discussions at management level.

14. Counterfeit or manipulated products

The Contractor must ensure that no counterfeit or manipulated products are delivered to the Client. Should counterfeit or manipulated products nevertheless be delivered by the Contractor to the Customer, the Contractor shall be fully liable for the resulting damage.

15. Complaint handling

The Client's complaint to the Contractor is processed with a test report, which shall be enclosed with the returned goods or submitted by email on the following day at the latest. Complaints without return delivery shall also be made with test report preferably by email.

The Client is entitled to return the goods without an RMA number (Return Material Authorisation). All information concerning replacement deliveries must be addressed to the buyer in charge and the Client's complaint processing office.

Requested 8D reports must be sent within the deadline specified in the test report by email with attached Word, Excel or PDF file, stating the test report number and Client article number, to the person in charge named in the test report.

The Client is entitled to charge all costs resulting from the complaint to the Contractor in accordance with the costs-by-cause principle. Furthermore, the Client is entitled to charge the Contractor a lump-sum handling fee of € 150 for each justified complaint.

16. Defect analysis

Defect analyses are initiated and monitored by the Contractor at the manufacturer's premises. For this purpose, the Client shall provide sufficient samples or – if available – its own test results.

17. Audits

(1) The CONTRACTOR allows the CLIENT to determine by means of audits whether its quality assurance measures meet the requirements of the CLIENT. The audit shall be announced in good time and includes the CONTRACTOR's complete process of service provision. Audits are based on the relevant standards, specifications and contractual arrangements between the contracting parties.

(2) The CLIENT shall inform the CONTRACTOR in writing of the results of these audits. If this audit necessitates corrective measures, the CONTRACTOR undertakes to immediately take corrective and preventive measures to implement them in due time and to inform the CLIENT thereof in writing. The CONTRACTOR must provide objective written proofs for the corrective and preventive measures initiated.

(3) At the request of the CLIENT, the CONTRACTOR shall actively support the preparation and implementation of third-party audits, e.g. by transmitting copies of documents, providing contact persons and access to all relevant information that serves as proof of the implementation of the contractual content. The costs for the third-party auditor shall be borne by the CLIENT.

(4) Audits of other customers and certificates can be recognised after examination by the CLIENT.

(5) Within the framework of its deliveries, the CONTRACTOR is prepared to carry out an audit of its subcontractors together with the CLIENT after consultation.

(6) Upon request, the CONTRACTOR shall grant the competent supervisory authorities or the "Notified Bodies" responsible for the CLIENT in accordance with the Medical Devices Implementation Act or comparable regulations the possibility, without prior notice, to audit the facilities in which relevant products are manufactured and the CONTRACTOR's quality management system and to inspect all relevant technical documents relating to the products or the quality management system. This also means that the CONTRACTOR must ensure that the same rights are enforced at its subcontractors.

(7) The documents and information exchanged between the CONTRACTING PARTIES as part of the audit are subject to confidentiality in accordance with the regulations agreed between the CONTRACTING PARTIES.

GREIPL GmbH:

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(Date)

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(Signature)

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(Name of the signatory in block capitals)

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(Function/title)

Contractor

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(Date)

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(Signature)

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(Name of the signatory in block capitals)

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(Function/title)