

Quality Assurance Agreement (QAA)

between

GAUDLITZ GmbH
Callenberger Straße 42
96450 Coburg

as well as all enterprises associated with
GAUDLITZ GmbH

- hereinafter called GAUDLITZ or Ordering Party -

and

- hereinafter called Supplier or Deliverer -
(Plant, division or other organisational unit of the Supplier to which this Agreement shall
exclusively apply)

- both hereinafter called „the Parties“ -

I. Policies

1. This quality agreement is a contractualization of the technical and organisational framework conditions and processes between GAUDLITZ and the Supplier, which are necessary for achieving the intended quality objective. It is a contractualization, including the attached annexes, between the Supplier and all enterprises associated with GAUDLITZ.
2. According to the technical documents agreed in writing, the Supplier is responsible for the accurate execution of his products and services. The contracting parties agree that the Ordering Party can rely on the attributes' safeguard of the contractual products by the final inspection executed by the Supplier and that intensive quality receiving inspections with the Ordering Party can be omitted.
3. The conclusion and execution of this agreement do not constitute any claim of the Supplier to placing orders for delivery items.
4. The alignment of the GAUDLITZ management system to the requirements of ISO 9001, ISO/TS 16949, ISO 14001 and ISO 13485 clarifies that quality and environmental protection are respectively important in all GAUDLITZ business areas. GAUDLITZ also expects an appropriate behaviour from his suppliers.

II. Scope

1. This agreement shall apply in conjunction with the individual order with regard to all the products and services to be delivered by the supplier (subjects of the contract) during the whole term of this agreement.
2. The Products shall conform to the agreed description (e.g. specifications, data sheets, drawings) and/or the agreed samples. According to the technical documents agreed in writing, the Supplier is responsible for the accurate execution of his products and services.

The Supplier has to know the product requirements and ask GAUDLITZ in order to inform himself in case of uncertainties. The Supplier shall, in every instance, check whether a description given by the Ordering Party is faulty, unclear, incomplete or not conforming to the sample. If the Supplier discovers any such deficiency, he shall, without delay, inform the Ordering Party thereof in writing.

III. Quality Assurance

1. The Supplier shall maintain a quality management system that satisfies the requirements specified in Annex 1 hereto. He shall manufacture and inspect the Products in conformity with the rules of the said quality management system. The Supplier shall, without delay, make sure that the said requirements are compatible with his quality management system.

2. If the Supplier purchases for the manufacturing or quality assurance of the Products previous supplies (semi-finished goods, software, services, manufacturing or inspection equipment or other previous supplies) from Third Parties (upstream suppliers), then the Supplier ensures the quality of such previous supplies either with his own methods or by contractual involvement of the upstream supplier into the supplier's quality assurance system.
3. The Supplier is fully responsible for his delivered product or for his services provided.
4. The Supplier shall keep a record of the performance of the abovementioned quality assurance measures, especially of measured data and inspection results, and keep this record, as well as samples (if any) of the Products, in a clearly arranged fashion. He shall, if requested and to the extent necessary, lay the record open to inspection by GAUDLITZ, and hand over the copies of the record and samples (if any). He shall preserve the record and samples for the periods specified in Annex 1 hereto.
5. The Supplier shall align his QM-system with the zero-defect-target. The PPM Agreement made in Annex 2 shall form a part of this Quality Assurance Agreement. The arrangement of quality objectives and measures, as well as action control limits (failures, ppm-objectives, etc.), including deviation permits or production permits, do not release the Supplier from his liability for warranty and compensation claims of GAUDLITZ due to deficiencies of the delivery.

IV. Supplier's Obligation to Furnish Proof and Information

1. The Supplier shall, at appropriate intervals, make it possible for the Ordering Party and its customers, if necessary, to satisfy itself of the performance of the herein mentioned quality assurance measures. For this purpose, the Supplier shall, to an appropriate extent and at previously agreed dates, grant the Ordering Party access to his business premises, and put a competent member of his staff at the Ordering Party's disposal for assistance during such an access. The Supplier is entitled to refuse access to any manufacturing processes not to be disclosed, or other business secrets.
2. The right to refuse the access to the documentation will be omitted, as soon as there is an interest of the competent authority for medical devices. The persons assigned with the inspection of medical devices are authorized,
 - (1) to enter and inspect properties, offices, premises, means of transport, and also in order to prevent imminent peril for public order and safety, living space during the conventional business hours, where an activity on/for medical devices is performed. The fundamental right of inviolability of the home (article 13 German Basic Law) is in this respect limited,
 - (2) to check medical devices, especially put into operation, as well as to take samples,
 - (3) to have access to the documentation about the development, production, investigation, clinical investigation, performance evaluation or purchase, preparation, storage, packing, putting into circulation and other remains of the medical devices, as well as about the circulating advertising material and to create transcripts or copies hereof, to demand all necessary information, especially about the operating actions mentioned in section (3).

3. The Ordering Party shall inform the supplier (or provide such information) in time and in written form about any changes of the requirements.
4. The Supplier shall inform the Ordering Party about changes within the agreed system or the procedures for the quality assurance as well as about changes of basic materials, manufacturing methods, vendor parts, data sheets and other documents, as well as about changes of the manufacturing location or the subcontractors. Therefore the information has completely to be effected in time, so that the Ordering Party is able to check it for the consequences and to disagree before the respective change will be applied to the subjects of the contract.

V. Quality problems

1. In case of deviations from the product- or the performance specification (drawing, technical terms of delivery, material, material properties, etc.) or from released procedures, the Supplier shall obtain a written deviation permit from GAUDLITZ before delivering the products. Potential arising expenditures which result from granting the deviation permit shall be at the Supplier's expense.
2. If the Supplier or his subcontractor detects an increase in deviations of the actual condition of the Products from their specified condition (quality fall-offs), he shall, without delay (within 24 hours), inform the Ordering Party thereof and about the remedial action he intends to take.

Until those corrective actions will take effect, the Ordering Party is able to demand special measures (e.g. higher testing frequency) for an appropriate period. It shall be for the Supplier to prove the restored accuracy of the contractual products and the achievement of the arranged quality level. Hereby arising additional costs are at the Supplier's expense, provided that the quality fall-off was not verifiably caused by the Ordering Party.

3. The Supplier shall, by marking the packing (traceability) or, if this should be impossible or inappropriate, by other suitable measures, take care to ensure that, as soon as any non-conformity of any of the Products occurs, he can identify which further Products might be affected. The Supplier shall inform the Ordering Party about his marking system or other measures, so as to enable the Ordering Party to carry out its own investigations to the extent necessary.

In the event of a quality problem, there shall be the possibility of access to lot and production data within one working day. Insofar as the problems issue from the quality of the products, the contracting parties are obliged to elaborate on approaches within one working day after appearance of the problem. The Supplier shall ensure that a short-term access to resources for inspecting and analyzing defects will be guaranteed at any time.

4. In the event of complaints, GAUDLITZ shall ask the Supplier for the presentation of an 8D report. The deadlines set therein, shall be considered by the Supplier. If it is not possible for the Supplier to meet the set deadlines, thus he shall communicate this in combination with a well-founded interim report. Final reports of error analyses shall to be meaningful, conclusive and complete with regard to contents.

5. For every justifiable complaint, the accrued additional costs shall be charged to the Supplier's account. Additionally accruing efforts or damages on the premises of GAUDLITZ and / or its customers, due to defective products of the Supplier, shall be charged to the Supplier's account. The Supplier ensures that he has contracted a product liability insurance at an appropriate amount.

VI. Makeshift manufacture

The Supplier agrees to cede the actual possession of the tools and production facilities to GAUDLITZ or a Third Party, jointly to be determined, in the event of process interruptions due to fire, water, force of nature or comparable incidents, which the Supplier could not foresee and give rise to delivery problems with GAUDLITZ. Borrowing the tools and the production facilities does not lead to conveyance.

As soon as the Supplier is able to produce again, GAUDLITZ shall return the lent tools and production facilities to the Supplier.

VII. The Ordering Party's Goods Inwards Inspection

1. GAUDLITZ shall, immediately after the receipt of Products, inspect whether they conform to the quantity and type ordered (identity check), and whether they externally show any bearing failures, transport damages or other defects of the delivered goods. Insofar as the Parties hereto think further inspections by the Ordering Party advisable, such inspections shall be additionally stipulated in writing.
2. The Supplier's final inspection is the last inspection which takes place prior to the final processing and replaces the functional goods inwards inspection with GAUDLITZ. GAUDLITZ is not responsible towards the Supplier for further tests and indications than named above.
3. Gaudlitz commits to the notification of defects in case of fault detection within 5 days.

VIII. Test method

The test methods and the utilized test mediums are to be coordinated with GAUDLITZ. For the special features the execution of measuring instrument capability studies is necessary in proof of reproducible measurement results with given measurement uncertainty. The test mediums have to be provided by the Supplier or be present and be subject to a systematical monitoring of the inspection equipment.

IX. Requalification

All Products have to undergo a regular and complete, dimensional and functional test pursuant the control plans of the Supplier considering the applicable customer specifications of material and function. On demand, the results are to be made available for GAUDLITZ. The dimensional tests contain the entire measurement of the whole product mass listed in the developmental documents.

X. Secrecy

1. Either Party hereto shall use all information to be treated as confidential received in connection with this Agreement exclusively for the purpose of this Agreement, and, if the other Party declares them as confidential or is obviously interested to keep them secret, shall prevent their being disclosed to third parties with the same care that it would apply to protect its own information. This obligation shall become effective upon the first receipt of any documents or information and shall expire 36 months after the termination of this Agreement.
2. The said obligation shall not apply to information that are generally known, or were already known to the receiving party at the time of their receipt while it was not under a secrecy obligation, nor to documents and information received afterwards from a third party entitled to disclose them, nor to documents and information developed by the receiving party without using any of the other party's confidential documents or information.

XI. Quality assurance officer

Either party shall, in writing, appoint a quality assurance officer, whose task it shall be to coordinate the performance of this Agreement and to make or bring about decisions in connection therewith. A change of the officer shall, without delay, be communicated in written form.

XII. Duration of the Agreement

1. This Agreement shall be concluded for an indefinite period.
2. Either party may terminate this Agreement at the end of the respective term of the supply contract, giving three months' notice.
3. This quality assurance agreement replaces the already existing quality assurance agreements between the parties and their applicable documents and attachments.
4. If one regulation of this Agreement is totally or partially ineffective, the validity of the remaining provisions shall not be affected. In this case, the parties undertake to replace the ineffective regulations by those, which meet closest the economic purpose of the invalid regulation.
5. Changes and supplements of this quality assurance agreement – including this clause – are to be made in writing.
6. For this Agreement, the law of the Federal Republic of Germany shall be applicable. The application of the convention of the United Nations about Contracts for the International Sale of Goods (CISG) is excluded.
7. Exclusive court of jurisdiction for all disputes pertaining to the contractual relationship is Coburg. However, GAUDLITZ is entitled to sue the Supplier at every other legal court of jurisdiction.

XIII. Applicable documents

The above mentioned documents are an essential object of contract of this agreement.

Ordering Party

Coburg, the
Date

.....
Signature

Supplier

.....
Place, Date

.....
Signature