

QAA (suppliers / electro)
between

Zimmer GmbH
Im Salmenkopf 5
77866 Rheinau, Germany

(hereinafter referred to as "Zimmer")

and

(hereinafter referred to as "Supplier")

In the following, Zimmer GmbH and the Supplier will also be referred to as "Contracting Parties."

Preamble

This Quality Assurance Agreement – hereinafter referred to as QAA – specifies and governs all planned quality assurance measures between the Contracting Parties with the objective of ensuring the quality of products and product development.

It contains the contractual determination of the technical and organizational basic conditions between Zimmer and its Suppliers that are required to achieve the desired quality objective.

This agreement also describes the minimum requirements for the QM system of the Supplier.

§ 1 Objective and Scope of Validity

1. This agreement was concluded with the objective of founding a long-term, regulated supplier partnership of mutual benefit.
2. It governs both the quality requirements for all products and services that are rendered or delivered during its duration as well as the delivery conditions between Zimmer and the Supplier.
3. This QAA applies as a supplement to the General Terms and Conditions of Purchase of Zimmer, which are hereby recognized as such, and is a component of supply contracts.
4. Individual clauses of this QAA are not valid insofar as they contradict contracts, especially supply contracts, that take precedence. In order to meet special requirements, specific supplements (individual agreements) to this QAA can be agreed as an annex to the supply contracts.

§ 2 Quality/Environmental Management System of the Supplier

1. The Supplier is obligated to use a quality management system, e.g. as per DIN EN ISO 9001 in the currently valid version, or a system that allows the complete documentation of inspection results on a permanent basis. The Supplier shall be committed to the zero-defect objective and must continuously enhance his services for this purpose.

The Supplier is responsible to the full extent for compliance with this agreement and for the quality of the products and services delivered and rendered to Zimmer in accordance with the agreed specifications in the respective supply contract, the technical documents or in other instructions.

2. The Supplier shall keep a file for the parts and materials delivered/manufactured by it which comprises the following criteria:
 - Order number of the purchaser
 - Article number of the purchaser
 - Designation of the quantity/number of the delivery item
 - Delivery date

Zimmer shall be allowed to view these files as well as inspection documents upon request.

These records shall be retained for a period of at least 15 years. This retention period starts after the end of the calendar year in which the last entry was made in the file created due to the delivery.

3. Zimmer is committed to protecting the environment. Therefore, we also expect our suppliers to make a voluntary commitment to environmental protection in the form of an implemented environmental management system as per DIN EN ISO 14001 in its currently valid version or a comparable management system that ensures compliance with valid environmental regulations and the continual improvement of the supplier's environmental performance.
4. The Supplier shall comply with the currently valid legal regulations of the European Union and the Federal Republic of Germany with regard to its deliveries. These include, e.g. the REACH Regulation (Regulation EC No. 1907/2006), the legislation on the recovery and environmentally-friendly disposal of electric and electronic devices (ElektroG, WEEE 2012/19/EU) as well as the national implementation of the Directives 2011/65/EU and 2015/863/EU (RoHS 2).
5. The Supplier shall immediately inform Zimmer regarding relevant changes to goods, their delivery capability, possible use or quality due to legal regulations, e.g. the REACH Regulation, and coordinate suitable measures with Zimmer in individual cases.

§ 3 Quality Assurance by Subcontractors

1. The Supplier is obligated to demand that its subcontractors set up, maintain and further develop comparable quality management systems so that the fault-free nature of their purchased parts, raw materials and/or externally processed parts is ensured.
2. Zimmer can demand documented evidence from the supplier that the supplier is satisfied with the effectiveness of the QM system of its subcontractors or that the quality of its purchased parts is ensured via suitable measures.

§ 4 Implementation of Audits

1. The Supplier gives Zimmer the right to determine via a product and/or process audit with a term of notice of one week whether the QA measures of the Supplier correspond to the requirements of Zimmer. Hereby, appropriate limitations from the Supplier are accepted which ensure trade secrets.
2. The Supplier shall grant Zimmer and, where necessary, its customers access to all production sites, testing centers, warehouses and neighboring areas as well as access to quality-relevant documents that are associated with the provided service and/or delivery.
3. Audits from approved certification bodies shall also be taken into consideration.
4. If quality problems should occur that were caused by services from subcontractors, Zimmer has the option of performing a joint audit at the subcontractor with the Supplier.
5. Zimmer shall inform the Supplier of the results of the audit. If Zimmer believes that corrective measures are required because of the audit performed, the Supplier is obligated to immediately create an action plan, implement it in due time, convince itself of the effectiveness of the measures and inform Zimmer regarding this. If necessary, Zimmer can demand the creation and implementation of an action plan.

§ 5 Technical Specifications and Documentation

1. The specifications and tolerance specifications to be met by the Supplier can be found in the order or the technical documentation, which are part of the supply contract.
The supplier shall ensure that it always manufactures, checks and delivers according to the most recent valid orders and/or the provided technical documentation.
2. Any requirement deviating from the technical documentation or other specifications and/or agreements shall be clarified in advance between the Supplier and Zimmer.
3. All technical documentation must be kept in the strictest confidence by the Supplier. The forwarding of the same to third parties requires the previous permission of Zimmer.

§ 6 Tests and Documentation

1. The Supplier is responsible for defining his own testing concept to meet the agreed objectives and specifications. The supplier shall test all production parts and materials for defects before delivery. Common industry and/or agreed testing procedures shall be used here and documented.
2. For the first delivery of an article, sampling must take place and be documented in the form of an initial sample test report (ISTR).
The ISTR and the sample shall be sent to Zimmer for approval before series production begins. Series production is approved only after a positive result by Zimmer. As an alternative, the approval of the sampling by Zimmer can also take place at the Supplier on site in advance. Approval on site, however, does not replace the necessity for documentation in the form of an ISTR.

§ 7 Defects

1. In general, only raw materials, products and services that are without deviations and defects may be delivered to Zimmer.
2. All failures that are determined by the Supplier during testing shall be subjected to a corresponding error analysis by the Supplier. This analysis, the suggested and the implemented measures shall be recorded. Zimmer shall have access to these records if necessary.
3. Raw materials, products and services with quality defects may only then be delivered to Zimmer when the Supplier has submitted an approval of deviation in advance and when this has been approved by Zimmer.
4. The examination of Zimmer is limited to defects - deviating from § 377 German Commercial Code - that are obvious to an external appraisal including the delivery papers (e.g. transport /packaging damage, incorrect and short delivery).
Apart from that, it depends on the extent to which an inspection is feasible according to proper business procedures, taking into account the circumstances of the particular case. The duty to notify for defects found later on remains unaffected. The delivered parts and materials are first checked by Zimmer in inspection processes during manufacturing/assembly and/or in the final check. In this respect, the Supplier forgoes the objection to delayed complaints for defects found later on.
5. The objection (notification of defects) shall be deemed timely and without delay in all cases if it is sent in writing within 7 business days of discovery (concealed defect) and/or for obvious defects (see No. 4) within 3 business days from delivery.
6. If there is a complaint against the delivered goods and the cause of the deviation can be traced back to the Supplier, then the Supplier is obligated to repair immediately or provide a replacement.
7. In the case of a complaint, Zimmer shall send a complaint report to the Supplier. Rejected parts shall be returned to the Supplier in the agreed scope. The Supplier is obligated to analyze each deviation and quickly inform Zimmer in an 8D report, but no later than within 5 business days, regarding the cause of the deviation and the introduced remedial and preventative measures, as well as immediately check on their effectiveness.

The Supplier shall inform Zimmer at regular intervals (weekly) with an updated 8D report regarding the processing status of the complaint.

8. If the parts delivered by the Supplier do not correspond to the specification or cannot be fitted due to the fault of the Supplier or are not suitable for later use and, therefore, this threatens to cause production interruptions at Zimmer or its customers, then the Supplier must seek a remedy through suitable immediate actions for which the supplier is responsible (e.g. substitute delivery, sorting and rework, special shifts, rush shipment, etc.). The Supplier shall bear the costs resulting from this. Notwithstanding this, the provisions in § 10 shall apply.

§ 8 Duty to Inform

1. If it becomes apparent that relevant agreements cannot be fulfilled, e.g. delivery schedules, quality features and supply quantities as well as deadlines for complaint processing, the Supplier is obliged to inform Zimmer of this and of the relevant circumstances without delay.
2. For production parts, over- and under-deliveries per order item in the amount of a maximum of $\pm 5\%$ shall be accepted. These shall be coordinated with Zimmer in advance.
3. Before changing production processes, materials or supply parts for products, before relocating production sites or production equipment as well as before changing testing and quality assurance processes, the Supplier shall inform Zimmer in a timely manner so that Zimmer can check whether the changes can have any negative results. Modifications to the product that mean a change to the form, fit and function (FFF) as well as fundamental changes that would entail a change in documentation for Zimmer require written approval from Zimmer.
4. Zimmer can object to a modification to one of the above mentioned points if these would have a negative effect on the product.
5. If Zimmer has not provided all the required information upon issuing the order with the Supplier or if this information is misleading or incorrect, the Supplier shall point this out immediately and request the required information from Zimmer and/or clarify the open points.

§ 9 Storage, Packaging and Transport

1. The Supplier shall ensure that the goods are packaged, stored and transported in a suitable means of transport to prevent damage, contamination, loss and quality degradation. The means of transport shall be marked so that the content can be identified at any time without considerable effort.
2. The Supplier shall ensure that the marking of the packaged products is also recognizable during transport and storage. The marking must have the following information:
 - Zimmer article number
 - QuantityDeliveries that contain products with various different article numbers shall be delivered with unique item separation.
3. All packaging materials must be environmentally friendly and 100% recyclable. Packaging that generates a high volume of waste as well as combinations of materials shall be avoided. In general, Zimmer opposes the use of packaging chips.
4. Euro containers that are the property of Zimmer may neither be affixed with labels nor inscribed. All information shall be listed on the delivery note only. The containers shall not be wrapped with adhesive tape, but rather closed with the associated lids and cable ties and/or strapped with plastic ties.
5. The Supplier shall be held responsible for damage caused by improper packaging as well as for any additional expenses for the incoming goods department at Zimmer as a result of non-observance with the above requirements.

§ 10 Defect Rights and Liability

1. The agreement of quality objectives and measures does not affect the liability of the Supplier with regard to warranty and damage claims by Zimmer because of defective delivery.
2. The Supplier is liable for all damages that Zimmer incurs as a result of a defective service and/or delivery. This includes all indirect and direct damages, including lost profit.

In particular, because of a defective delivery / service, Zimmer can demand compensation from the Supplier for the following:

- The costs resulting from sorting out the defective parts (sorting costs)
- The costs for replacement procurement if the Supplier cannot provide replacement procurement in a timely manner after consultation with Zimmer
- The costs for processed and finished products that are affected by a defective delivery / service (reject costs)
- The costs for disassembly and reassembly
- The costs for return shipment and other defective-related, incurred freight costs
- All other costs that incur for claims processing, including any additional administrative expenses

Damages that are subject to reimbursement also include the costs and/or damage that Zimmer must reimburse and/or compensate for its customers because of the Supplier's defective delivery/service.

3. According to the legal requirements, the Supplier is liable up to an amount of €5 million per claim for any damages that Zimmer incurs due to the delivery of defective production parts or materials. The Supplier shall obtain and maintain a global business and product liability insurance policy with a lump-sum coverage of at least €5 million per personal injury/material damage. On the request of Zimmer, the Supplier shall present the insurance policy.
4. Contractual claims due to defect liability shall lapse after 3 years from the transfer of risk. The regular statutory limitation period and the respective statutory start of the statute of limitation (§§ 195, 199 German Civil Code) shall apply to any non-contractual claims Zimmer may have for damages on account of defects, unless the application of the limitation periods under the law governing the sale of goods leads in a particular case to a longer limitation period.
5. The liability provisions for reimbursement of damage and expenses result from the legal regulations. The Supplier is only liable for reimbursement of damage and expenses for each type of breach of duty (pre-contractual, contractual and non-contractual) in the case of gross negligence and willful misconduct by it or its vicarious agents. Deviating from this, the Supplier is liable for all forms of negligence in the event of damage to life, body and health or the violation of a contractual obligation that endangers the achievement of the purpose of the contract (essential contractual obligation). The liability according to the German Product Liability Law remains unaffected by this.

§ 11 Period of Validity

1. This Quality Assurance Agreement is valid for an unlimited period. However, it can be canceled by any of the Contracting Parties in writing three months before the end of the calendar month.
2. The cancellation of this agreement does not affect the effectiveness of current individual contracts and/or supply contracts up to their completed processing.

§ 12 Confidentiality

1. Unless otherwise specified in the supply contracts, both parties are obliged to keep confidential all information provided by the other party, including the content of this agreement, and to only use this information in the interest of the existing contract terms between the parties. This confidentiality requirement also extends, in particular, to business and trade secrets, financial relationships, prices, the customer base as well as other technical and economic information.
2. The Supplier shall also commit its subcontractors to confidentiality.

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3. This confidentially declaration shall remain valid until such time as the respective partner releases the other from the confidentiality obligation.

§ 13 Final provisions

1. Amendments as well as supplements to this agreement must be made in writing.
2. If one or more provisions of this contract are or become ineffective, this does not affect the validity of the other provisions.
3. The law of the Federal Republic of Germany applies to this agreement and the legal relationships resulting from the contractual relationship.
4. All disputes arising from of the agreement shall be decided before the Court responsible for Zimmer's business location. However, Zimmer is also entitled to file suit at the Supplier's headquarters. Any mandatory provisions of applicable law providing for exclusive places of jurisdiction shall remain unaffected by this regulation.

(Location, Date)

(Location, Date)

(Signature "Zimmer")

(Signature Supplier)