

between

Zimmer GmbH
Im Salmenkopf 5
77866 Rheinau

(hereinafter referred to as Zimmer GmbH)

and

«Lieferant»
«Straße»
«PLZ» «Ort»

(hereinafter referred to as the supplier)

In the following, Zimmer GmbH and the supplier are also referred to as the parties to the contract.

Preamble

This quality assurance agreement - hereinafter referred to as the QAA - specifies and governs all of the quality assurance measures planned between the parties to the contract with the goal of assuring the quality of the products and of product development.

It contains the contractual specification of the technical and organisational framework conditions and processes between Zimmer GmbH and its suppliers which are necessary to achieve the quality targets aimed for.

The agreement also describes the minimum requirements of the QM system of the supplier.

1 Aim and scope

- 1.1 This agreement has been entered into with the aim of establishing a long-term, well-regulated supplier partnership of mutual benefit.
- 1.2 It governs the quality requirements for all products and services to be performed or supplied during its term as well as the terms of delivery between Zimmer GmbH and the supplier. Every agreement and specific changes and additions must be in writing; they must be agreed separately in annexes to this QAA.

2 Quality/environmental management system of the supplier

- 2.1 The supplier is obliged to put in place an ongoing quality management system, e.g. in accordance with the latest version of DIN EN ISO 9001, or a system which ensures complete documentation of test results. The supplier shall aim for a zero-defect target and optimise its services in this respect on a continuous basis.
- 2.2 The supplier itself is responsible in full for compliance with this agreement and for the quality of the products and services it supplies to Zimmer GmbH, in accordance with the agreed features in the respective contract for purchase, the technical documentation or in other specifications.
- 2.3 Zimmer GmbH has undertaken to protect the environment. We therefore expect our suppliers to likewise provide an undertaking to protect the environment in the form of an implemented environmental management system in accordance with the latest version of DIN EN ISO 14001 or a comparable management system which ensures compliance with the applicable environmental regulations and continuously improves the environmental performance of the supplier.
- 2.4 The supplier must also comply with the applicable statutory regulations of the European Union and the Federal Republic of Germany in its deliveries. These include e.g. the REACH regulation (Regulation EC No. 1907/2006), the German law on the return and environmental disposal of electrical and electronic equipment (ElektroG) being the national implementation of Directive 2011/65/EU (RoHS 2) and Directive 2002/96/EC (WEEE).
- 2.5 The supplier will immediately inform Zimmer GmbH of relevant changes to the goods, their availability, usability or quality occasioned by statutory regulations, e.g. by the REACH regulations, and will agree appropriate steps with Zimmer GmbH in individual cases.

3 Quality assurance by sub-suppliers

- 3.1 The supplier will instruct its sub-suppliers to comply with the obligations entered into under this contract.
- 3.2 Zimmer GmbH may demand documentary evidence from the supplier that the supplier has satisfied itself as to the effectiveness of the QM system in place at its sub-suppliers or that it has taken appropriate steps to ensure the quality of purchased parts.

4 Carrying out of audits

- 4.1 The supplier grants Zimmer GmbH the right to determine by means of a product or process audit whether the QA measures of the supplier meet the requirements of Zimmer GmbH. Reasonable restrictions by the supplier in order to safeguard business secrets will be accepted.
- 4.2 Audits from approved certification bodies will also be taken into account.
- 4.3 If quality issues arise which have been caused by the services of sub-suppliers, Zimmer GmbH has the option to conduct a joint audit with the supplier on the sub-supplier's premises.

5 Technical features and documentation

- 5.1 The quality features and tolerance specifications to be complied with are to be taken from the order or the technical documentation which forms part of the contract for purchase. The supplier shall ensure that it always produces, tests and supplies in accordance with the latest valid orders and the associated technical documentation.
- 5.2 Any request which deviates from the technical documentation or other specifications or agreements must be clarified with Zimmer GmbH by the supplier.
- 5.3 All technical documentation, as specified above, must be treated by the supplier in the strictest of confidence. Disclosure to third parties must be approved by Zimmer GmbH in advance.

6 Tests, documentation and action to be taken

- 6.1 The supplier must develop a test concept on its own behalf in order to achieve the agreed targets and specifications.
- 6.2 If the supplier is preparing parts from drawings, it must document the test results in a protocol and include this with the delivery.

- 6.3 When an article is supplied for the first time, a sample inspection must take place and be documented in the form of an initial sample inspection report (ISIR). The ISIR and the samples must be sent to Zimmer GmbH for approval before commencing series production. Only after a positive finding by Zimmer GmbH is series production approved. The approval of the samples may alternatively be conducted by Zimmer GmbH on site at the supplier's premises. Approval on site does not dispense with the need for documentation in the form of an ISIR.
- 6.4 Zimmer GmbH tests the products purchased from the supplier upon receipt for compliance in terms of quantity and identity and for externally visible defects. The values documented in the protocol at 6.2 are tested by Zimmer GmbH on a random basis.
- 6.5 The obligation to store the specification and certification documents lasts for 5 years. The supplier must grant Zimmer GmbH sight of these documents on request.

7 Defects, deviations in respect of quality and supply

- 7.1 As a general rule, only raw materials, products and services which are free of defects and deviations from the required standard of quality may be supplied to Zimmer GmbH.
- 7.2 Raw materials, products and services with quality defects may only be supplied to Zimmer GmbH if the supplier has previously applied for a deviation and this has been approved by Zimmer GmbH.
- 7.3 Defects in a delivery must be notified immediately by Zimmer GmbH to the supplier as soon as they have been identified in the normal course of business. In this regard the supplier waives its objection to the late notification of defects.
- 7.4 If a complaint is ultimately lodged about the goods supplied and if the cause of the defect lies demonstrably with the supplier, it is obliged to immediately fix it or to provide a replacement. Zimmer GmbH is entitled in this regard to charge the supplier with the costs of processing the complaint in the form of a flat complaint charge in the sum of EUR 75. Additional costs incurred as a result of the complaint, e.g. reworking, will be charged to the supplier separately. Such charges will be agreed by Zimmer GmbH in advance with the supplier.
- 7.5 In the event of a complaint Zimmer GmbH will send a complaint report to the supplier. The first response must be within 24 hours. An 8D report with the corrective measures taken will be expected by Zimmer GmbH within 5 working days.

8 Duty to inform

- 8.1 If it becomes apparent that agreements on delivery, quality features and supply quantities as well as deadlines for processing complaints cannot be adhered to, the supplier is obliged to proactively inform Zimmer GmbH of this and of the exact circumstances.
- 8.2 For production parts, a maximum of $\pm 5\%$ above or below the agreed supply quantity will be accepted for each item ordered. However this must be agreed with Zimmer GmbH in advance. In the area of surface coatings Zimmer GmbH will accept a rejection rate of a maximum of 3% for small parts.
- 8.3 The supplier shall inform Zimmer GmbH well in advance of any changes to the production process, materials or third-party parts for the products, relocating production facilities or production equipment or changing test procedures or quality assurance procedures so that Zimmer GmbH can check whether the changes could have a negative effect.
- 8.4 Zimmer GmbH may refuse a change to one of the points mentioned above if this could have a negative effect on the product.

9 Storage, packaging and transport

- 9.1 The supplier shall ensure that the goods are packed, stored and transported using suitable means of transport in order to avoid damage, contamination, loss and reductions in quality. The means of transport must be labelled so that their contents are identifiable at all times.
- 9.2 The supplier must ensure that the labelling of the packaged products is also identifiable during transport and storage. The labelling must contain the following details: Zimmer GmbH item number and quantity. Deliveries which contain products with different item numbers must be supplied with a clear separation of the items.
- 9.3 All packaging material must be environmentally friendly and 100% recyclable. Packaging which creates a lot of waste and combinations of different materials should be avoided. Zimmer GmbH disapproves in general of the use of packaging chips.
- 9.4 Euro containers which are the property of Zimmer GmbH must not have stickers attached or be written on. All information must be written on the delivery note. Adhesive tape must not be wound around the containers, instead they should be closed with the relevant lids and cable ties or strapped with non-metallic strapping.
- 9.5 Damage caused by improper packaging or increased costs in the Zimmer GmbH goods inward department resulting from a failure to comply with the instructions above may be absorbed by the supplier.

10 Liability

- 10.1 The agreement of quality targets and measures to be taken does not affect the liability of the supplier for claims of the customer under guarantee or in respect of compensation for damages due to defects in the delivery.
- 10.2 If consequential damage is incurred as a result of a defective product supplied by the supplier, the supplier shall be liable to the full extent of the law.
- 10.3 Suppliers who receive parts from Zimmer GmbH for reworking must certify that they have extended product liability insurance, which must cover a minimum insured sum in the amount of the average value of the parts in circulation with the supplier.

11 Term and changes to the agreement

- 11.1 This quality assurance agreement is unlimited. It may however be terminated by each of the parties to the contract in writing giving a notice period of three months. The ending of this agreement does not affect the validity of individual ongoing contracts until they are completed.
- 11.2 Amendments or additions to this agreement must be in writing.

12 Non-disclosure clause

The confidential affairs, processes and financial circumstances of each of the parties to the contract must be treated in confidence. This non-disclosure clause applies in particular to business and trade secrets, financial circumstances, prices and customer base.

The supplier will likewise bind its sub-suppliers to this non-disclosure clause.

The non-disclosure clause remains in effect until the respective other party releases the other from the obligation of non-disclosure.

13 Severability clause

Should one or more provisions of this contract be or become legally invalid, this does not affect the validity of the remaining provisions.

2 Quality/environmental management system of the supplier

- 2.1 The supplier is obliged to put in place an ongoing quality management system, e.g. in accordance with the latest version of DIN EN ISO 9001, or a system which ensures complete documentation of test results. The supplier shall aim for a zero-defect target and optimise its services in this respect on a continuous basis.
- 2.2 The supplier itself is responsible in full for compliance with this agreement and for the quality of the products and services it supplies to Zimmer GmbH, in accordance with the agreed features in the respective contract for purchase, the technical documentation or in other specifications.
- 2.3 Zimmer GmbH has undertaken to protect the environment. We therefore expect our suppliers to likewise provide an undertaking to protect the environment in the form of an implemented environmental management system in accordance with the latest version of DIN EN ISO 14001 or a comparable management system which ensures compliance with the applicable environmental regulations and continuously improves the environmental performance of the supplier.
- 2.4 The supplier must also comply with the applicable statutory regulations of the European Union and the Federal Republic of Germany in its deliveries. These include e.g. the REACH regulation (Regulation EC No. 1907/2006), the German law on the return and environmental disposal of electrical and electronic equipment (ElektroG) being the national implementation of Directive 2011/65/EU (RoHS 2) and Directive 2002/96/EC (WEEE).
- 2.5 The supplier will immediately inform Zimmer GmbH of relevant changes to the goods, their availability, usability or quality occasioned by statutory regulations, e.g. by the REACH regulations, and will agree appropriate steps with Zimmer GmbH in individual cases.