

between

Zimmer DS GmbH Daempfungssysteme

Im Glockenloch 2

77866 Rheinau

(referred to below as Zimmer DS)

and

«Lieferantename»

«Straße»

«PLZ» «Ort»

(referred to below as the supplier)

Zimmer DS and the supplier are also referred to below as the parties.

Preamble

This Quality Assurance Agreement – referred to below as QSV – states and regulates all the quality assurance action foreseen by the parties to ensure the quality of the products and of the product development process.

It contains the contractual determination of the framework technical and organisational conditions and processes agreed between Zimmer DS and its suppliers to achieve the quality goals strived for.

The Agreement also describes the minimum requirements on the supplier's quality system.

The supplier must perform its quality assurance action in such a way that its products are faultless, that they conform to the specifications stipulated by Zimmer DS and that every product is provided

- in the agreed quantity
- at the agreed date

- at the agreed place
- in the agreed execution
- in the agreed packaging and labelling.

This aim is to achieve a zero rate of errors and bring about continuous improvements in performance.

1 Aim and area of application

- 1.1 This Agreement is concluded with the aim of establishing a regulated supply partnership oriented to the long term which benefits both parties.
- 1.2 It regulates both the quality requirements for all products and services that are delivered or provided during its term of validity and also the delivery conditions between Zimmer DS and the supplier. Every auxiliary agreement and all specific amendments or supplements require the written form. Such must be agreed separately as riders to this QSV.

2 The supplier's quality/environmental management systems

- 2.1 The supplier is obliged to permanently maintain a quality system (e.g. pursuant to DIN EN ISO 9001 in the prevailing version), or to operate a system that comprehensively documents the results of all tests. The supplier shall aim for a zero rate of errors and improve its performance continuously to achieve this end.
- 2.2 The supplier is responsible to the full extent for conforming to this Agreement and for the quality of the products and services it delivers to Zimmer DS, in accordance with the characteristics agreed in the respective purchase contract, in the technical documents or in other stipulations.
- 2.3 Zimmer DS is committed to protecting the environment. We therefore expect the same commitment to environmental protection from our suppliers in the form of an implemented environmental management system pursuant to DIN EN ISO 14001 in the prevailing version, or of a comparable system, which ensures compliance with current environmental legislation and continuously improves the supplier's environmental behaviour.
- 2.4 The supplier's deliveries must conform to the prevailing legal regulations of the European Union and of the Federal Republic of Germany. An example of such is the REACH Regulation (EC) No. 1907/2006.
- 2.5 The supplier shall inform Zimmer DS without undue delay of any relevant changes to the goods, their availability for delivery, their intended use or quality caused by legal regulations (e.g. by the REACH Regulation) and, if necessary, agree suitable action with Zimmer DS.

Evaluation of quality performance

A decisive factor in the attainment of quality goals by an industrial undertaking is the quality performance of its suppliers.

It is therefore essential to evaluate a supplier's quality performance for this purpose.

Selected suppliers are assessed under a uniform system consisting of two blocks. The first block is made up of data relevant to quality derived from CAQ (computer-aided quality assurance) and is worth 50% of the overall assessment. The second block comprises commercial criteria (on-time deliveries, delivery of the agreed quantities, environmental aspects, general service and how projects are processed) and is likewise worth 50% of the overall evaluation of the supplier.

The "A", "B" or "C" categories have the following meanings:

- a. Categorisation in "A"

An "A-supplier" fulfils the main prerequisites for a long term supply relationship with Zimmer and strives for continuous improvement in order to achieve the goal of a "zero rate of errors".

b. Categorisation in "B"

Although a "B-supplier" is still acceptable, there are nevertheless weaknesses in its quality assurance system. Improvements must be made as a matter of urgency. The supplier must demonstrate its readiness to achieve the quality status "A" in collaboration with Zimmer DS. If a supplier is categorised in "B", it is required to notify Zimmer DS within four weeks in writing of the action it intends to take and when it expects to achieve the quality status "A".

c. Categorisation in "C"

A "C-supplier" is unacceptable because there are major weaknesses in its quality assurance system. The Purchasing Department at Zimmer is required to find alternative suppliers. The aim here is to replace such suppliers with better qualified ones.

3 Quality assurance at sub-suppliers

- 3.1 The supplier shall instruct its sub-suppliers to conform to the obligations to which it is subject under this Agreement.
- 3.2 Zimmer DS can demand documented evidence from the supplier to demonstrate that it has established the effectiveness of the quality systems deployed by its sub-suppliers or has ensured the quality of its bought-in parts by means of suitable action.

4 Performance of audits

- 4.1 The supplier grants Zimmer DS the right to perform product and/or process audits in order to establish whether the supplier's quality action conforms to the requirements of Zimmer DS. Reasonable restrictions imposed by the supplier in order to safeguard its operating secrets shall be accepted in this context.
- 4.2 Audits by approved certification bodies can likewise come into consideration.
- 4.3 If quality problems occur that are caused by a sub-supplier's work or services, Zimmer DS is allowed to perform a joint audit of this sub-supplier together with the supplier.

5 Technical characteristics and documents

- 5.1 The characteristics relevant to quality and the tolerance specifications to be observed by the supplier are stated in the order or in the technical documents. These are a component of the purchase contract. The supplier assures that it will manufacture, inspect and deliver in accordance with the currently valid orders and/or to the technical documents available to it at all times.
- 5.2 The supplier must clarify every issue that deviates from technical documents or other specifications or agreements with Zimmer.
- 5.3 The supplier must treat all technical documents, as stated above, in absolute confidence. Permission must be obtained from Zimmer in advance before such are passed on to third parties.

6 Inspections, documentation and action

- 6.1 The supplier shall determine a test schedule, under its own responsibility, to ensure that the agreed goals and specifications are fulfilled.
- 6.2 A sample must be submitted before an article is delivered for the first time and documented in the form of a First Sample Test Report (EMPB). The EMPB and the samples must be sent to Zimmer for release before series production commences. Series production shall not be released until samples have been approved by Zimmer DS. Alternatively, Zimmer DS can release samples in advance in the supplier's works. However, release in the supplier's works does not replace the requirement of documentation in the form of an EMPB.
- 6.3 Zimmer DS shall inspect the products procured from the supplier after their receipt to verify their quantity and identity and to check for any outwardly visible defects. Zimmer DS shall make spot checks on the values documented on the protocol stated in 6.2.
- 6.4 The period of retention for specifications and documents serving as evidence is 5 years. Upon request, the supplier shall allow Zimmer DS to inspect these documents.

7 Defects, non-conformities in quality and in deliveries

- 7.1 In principle, the raw materials, products and services delivered to Zimmer DS may not have any quality non-conformities or defects.
- 7.2 Raw materials, products or services with quality defects may not be delivered to Zimmer DS unless the supplier has applied for a deviation permit and this has been granted by Zimmer DS.
- 7.3 Zimmer DS shall notify defects in a delivery to the supplier without undue delay, as soon as these have been found in the course of regular operations. The supplier insofar waives the objection of a complaint made too late.
- 7.4 If a complaint is lodged concerning delivered goods and the supplier is demonstrably responsible for the cause of the non-conformity, the supplier is obliged to immediately undertake rework or make a replacement delivery. Costs incurred because of a complaint (e.g. due to subsequent work or extra journeys) will be charged separately to the supplier. In principle, Zimmer DS shall agree such charges with the supplier in advance.
- 7.5 In case of complaints, Zimmer DS shall send a complaint report to the supplier. The supplier must submit an initial response within 3 work days. Zimmer DS expects an 8D report detailing the corrective action taken within 14 work days.
- 7.6 Although a zero error strategy should be pursued as a matter of principle, this cannot always be completely ensured in practice, not even with 100% inspections. For this reason, realistic and practicable limits shall be agreed.

It is agreed between Zimmer DS and the supplier that a limit value of 100 ppm in total is admissible for features relevant to functioning and processing and for critical characteristics in the assembly process. The assessment period retrospectively reviews the quantity of pieces delivered and the quantity of parts complained of and returned in a quarter.

If this value is overshot, the production batch in question can be blocked and returned to the supplier. Additional costs incurred for this reason will be charged to the culprit. If it becomes apparent that agreements made (such as delivery dates, quality characteristics, delivery quantities or deadlines for rectifying complaints) cannot be kept to, the supplier is obliged to inform Zimmer DS of this and provide details of the circumstances.

- 7.6 The supplier shall notify Zimmer DS in good time before it makes changes to manufacturing processes, materials or bought-in parts for the products, before production sites or manufacturing equipment are relocated and before testing procedures or quality assurance processes are changed. Zimmer DS must be allowed sufficient time to establish whether such changes could have detrimental effects.
- 7.7 Zimmer DS can reject a change to one of the items stated above if such would have a detrimental effect on the product.

8 Storage, packaging and transport

- 8.1 The supplier shall pack, store and transport the goods in suitable transport packaging to ensure that they do not become damaged, soiled, lost or suffer any deterioration of quality. Transport packaging must be marked in such a way that the contents can be identified at all times.
- 8.2 The goods shall be marked with a label prescribed by Zimmer to ensure that the labelling of the packaged products can be recognised even during transport and storage. Labels must show the following details: Zimmer article number, quantities and batch number for traceability.
- 8.3 The supplier can be charged for damage or losses resulting from improper packaging and for additional expenses incurred in the Incoming Goods Department at Zimmer DS due to non-compliance with the aforesaid requirements.

9 Liability

- 9.1 The agreement of quality goals and action does not affect the supplier's liability for the customer's warranty claims and claims to damages due to defects in deliveries.
- 9.2 If consequential losses are suffered due to a defective product delivered by the supplier, the supplier is liable to recompense these within the framework of legal regulations, in accordance with the causative principle.

10 Duration and amendment of the Agreement

- 10.1 This Quality Assurance Agreement is concluded for an indefinite time. However, it can be terminated by either party by serving written notice of three months. Termination of this Agreement does not affect the validity of single orders still on-going, which shall be processed through to their completion.
- 10.2 Amendments and supplements to this Agreement require the written form.

11 Confidentiality

The confidential affairs, processes and financial circumstances of the opposite party must be treated in confidence. In particular, business and operating secrets, financial circumstances, prices and customers are subject to the obligation of secrecy.

The supplier shall in turn oblige its sub-suppliers to maintain secrecy.

The declaration of confidentiality applies until one party releases the other from the obligation of secrecy.

12 Salvatory clause

Should one or more provisions in this agreement be or become legally unworkable, this shall not affect the validity of the remaining provisions.

Rheinau, (date) _____

M. Graffy C. Boog

Place, date

Signature