

## Quality Assurance, June 2016

**Alber GmbH**  
**Vor dem Weißen Stein**  
**72461 Albstadt**

**1. General**

1.1 ALBER GmbH, Vor dem Weißen Stein 21, 72461 Albstadt-Taiffingen (hereinafter abbreviated to "ALBER") places great value on guaranteeing the continuous quality of the products to be supplied by the supplier to ALBER. In order to simplify the incoming-goods checks at ALBER and to guarantee quality, the following quality standards apply for contracts with suppliers.

1.2 Quality standards also serve in guaranteeing and use of the most environmentally-aware and resource-sparing processes and materials possible.

1.3 Quality standards or other deviating conditions of the supplier do not apply unless they have been expressly recognised by ALBER in writing. These quality standards also apply in all cases where ALBER accepts the supplier's deliveries without objecting to its conditions which deviate from these standards (regardless of whether they are known to ALBER or not). All references by the supplier to the application of its standards are hereby expressly objected to.

1.4 These quality standards apply to all deliveries of contract items which are ordered after this agreement enters into force and whose ordering is confirmed before the cessation of this agreement.

**2. Supplier's responsibility**

2.1 In order to guarantee the quality of its products to be supplied to ALBER, the supplier hereby undertakes on its own responsibility to maintain and/or apply an effective quality management system (QMS). Preferably, the evidence of this should be provided in the form of an ISO 9001 certification or higher (e.g. ISO 13485 or TS 16949). The efficacy of alternative quality management systems is to be proven separately by the supplier. ALBER hereby reserves the right, however, to check the efficacy of such a QMS in audits.

2.2 Equally, the supplier is to maintain a system which guarantees an economic handling of resources and the compliance with all relevant statutory provisions, also in the area of the environment, as well as waste and disposal. Ideally, the supplier shall have ISO 14001 certification as evidence of a functioning environment management system (EMS).

2.3 In principle, the supplier must assume that no incoming-goods checks (IGC) will be carried out at ALBER. In nearly all cases, only an identity and quantity check is carried out. For this reason, the supplier must ensure that the products supplied by it correspond 100% to the actual requirements laid down by ALBER and other statutory framework conditions (e.g. ROHS, REACH). The type and manner of the guarantee process shall be incumbent upon the supplier. The primary objective in this context should be a capable process which requires only a few random-sample checks by the supplier. If this cannot be fully guaranteed, the corresponding check expenditure is to be increased by the supplier.

2.4 The supplier shall be obliged to ALBER to pursue the zero-defects objective. Insofar as the zero-defects objective is not achievable in the short term, the supplier can set temporally-limited ceilings for defect rates as interim targets together with ALBER (e.g. ppm agreements). If the supplier recognises that the objectives set will not be achieved, it shall be obliged to present ALBER with concrete measure plans and to implement these.

2.5 Falling below agreed ceilings shall not release the supplier from its obligation to work through all complaints as well as to continue to pursue constant improvement. Agreement on quality objectives and measures as well as intervention thresholds shall not release the supplier from liability for quality defects and compensation claims by ALBER due to defects in deliveries and/or services.

2.6 The supplier shall be obliged to present ALBER with the supplier's certificate without request, and notice is to be given about updates in each instance directly after the expiry of the validity period or in the event that the certificate is revoked.

**3. Audits**

3.1 The supplier shall allow ALBER to check by means of audits at any time whether its QMS and its quality assurance measures satisfy ALBER's requirements. An audit can be carried out as a system, process or product audit. In the framework of this audit, subjects which are relevant to the environment will also be audited. Conducting such audits shall not result in the supplier's exclusive responsibility with regard to the quality of the products manufactured and supplied being detrimentally affected in any way.

3.2 Announcement by ALBER shall be given in a timely manner for this purpose. The supplier shall give ALBER access to all production sites, inspection bodies, warehouses and adjoining areas as well as inspection of quality-relevant documents which are associated with the service or product ordered. In principle, the supplier shall be responsible for the auditing of its sub-suppliers; nevertheless, the supplier shall give the opportunity for an audit to be carried out by ALBER of its sub-suppliers upon request by ALBER.

3.3 In the same scope, the supplier shall permit, when necessary, named bodies or authorities pursuant to the Medical Devices Directive 93/42/EEC, or FDA Quality System Regulation – 21 CFR Part 803 and 820, to carry out checks directly at its company with regard to the QM system or to the products and services which pertain to ALBER. Pursuant to Recommendation 2013/473/EU, this also pertains fully (see also 2013/473/EU, Annex III) to unannounced audits (on-site visits) at the supplier by named bodies.

3.4 ALBER is to be informed immediately by the supplier if the supplier has contact with authorities, named bodies or the FDA and if in that context materials, processes or products for ALBER are affected or influences are to be expected on ALBER products. In the event of an announced inspection of the supplier by authorities, named bodies or FDA inspectors and if influences on ALBER products are to be expected, ALBER is to be informed at least 14 days in advance, insofar as possible. Official written replies from the supplier to authorities, named bodies or to the FDA which can be associated with ALBER products or which contain ALBER's company name, logo or trademarks must be coordinated before dispatch by the supplier with ALBER, and may not be sent without ALBER's consent.

3.5 In this context, reasonable limitations of the supplier or the sub-supplier to safeguard its business secrets shall be accepted. ALBER shall inform the supplier of the findings of the audit. If in ALBER's view correction measures are necessary on the basis of the audit carried out, the supplier hereby undertakes to draw up an action plan without undue delay, to implement this in a timely manner, to convince itself of the efficacy of the measures and to notify ALBER about these. ALBER shall be able to request involvement in the drawing up and implementation of the action plan.

**4. Subcontracting orders**

4.1 Instructing sub-suppliers shall require ALBER's prior written consent. In this respect, the supplier shall be obliged to inform ALBER before instructing the respective sub-supplier about this. ALBER shall be able for an important reason to refuse consent to the instruction of a sub-supplier. An important reason shall be deemed to exist in particular if there are circumstances which give rise to doubts about the reliability of the sub-supplier.

4.2 ALBER shall be entitled to demand the immediate termination of the instruction of a sub-supplier if circumstances become known which give rise to doubts about compliance by the sub-supplier with the agreements arising out of this Agreement or the agreements otherwise entered into between ALBER and the supplier.

4.3 The supplier's responsibility and liability to ALBER shall not be affected as a result of instructing sub-suppliers.

4.4 In order to keep confidential the data regarding drawings, specifications, etc. of ALBER, the supplier must ensure that orders are only placed with sub-suppliers (e.g. regarding surface finishing) if there is a confidentiality agreement with the sub-supplier as well. This is to be proven upon request by ALBER. Moreover, insofar as possible, the supplier should draw up its own specification so that ALBER as the principal is made unrecognisable.

**5. Approvals, first samples, modifications, supplier chain, information flow**

5.1 If ALBER lays down a supplier chain and if applicable a system supplier during a project, then ALBER shall be able to exert influence on every individual supplier during the development. At the latest with the initial sampling, ALBER shall only give an approval to its direct supplier, which then has to be passed on from supplier to supplier along the chain. Thus, each supplier takes over all rights, obligations and risks of an ordinary business relationship with its partners.

5.2 In the event of an order being awarded to suppliers with sub-suppliers, the supplier shall be responsible for the quality of the products which it purchases, and must implement the requirements of this QAA at its sub-suppliers.

5.3 Initial samples are products manufactured and tested under serial production conditions (machines, systems, operating and inspection tools, processing conditions). The test results of all characteristics are to be documented. In order to guarantee that the measurement results can be compared, the measuring methods and the measuring tools are to be coordinated in advance.

5.4 The initial-sample documentation must contain the evidence and documents listed pursuant to Annex PPA, depending on the PPA level (in compliance with PPAP – PPA Parts and Process Approval). If necessary, ALBER shall provide assistance in connection with the first drawing up of this kind of documentation.

5.5 Before initial sampling, the manufacturing and testing conditions are to be coordinated between ALBER and the supplier and are to be documented.

5.6 The supplier shall at all times check all technical documents, such as drawings, specifications, piece lists and CAD data, after receipt for feasibility, and errors and risks as well as improvement possibilities which are identified in that context are to be notified to ALBER without undue delay. The same shall apply if it is unable to check/measure characteristics. Upon acceptance of the drawing, the supplier confirms that it is able to produce and to test the products on the conditions given in the order and the drawing in a process-reliable manner using the specified materials.

5.7 The supplier hereby undertakes to inform ALBER about environmentally-friendly manufacturing processes.

5.8 The supplier shall ensure that all of the nodes concerned in its organisation always have available the most recently-validated technical documents supplied by ALBER, and that at the time of a product modification, all documents which have become invalid as a result of the modification are removed. The supplier shall be obliged to check that it has all of the named documents at its disposal. In accordance with this procedure, the supplier shall be obliged to involve its subcontractors as well.

5.9 The supplier shall be obliged to confirm receipt of the modifications within two weeks and to present to ALBER again with the first delivery in accordance with current modification status all of the PPA documents which are affected by the modification.

5.10 The supplier hereby undertakes to obtain ALBER's consent before:

- modifying production processes/materials (including at sub-suppliers)
- changing sub-suppliers
- modifying testing processes/equipment
- relocating production locations
- moving production equipment at the location
- modifying production auxiliary materials
- modifying packaging, labelling,
- and to carry out an initial sample test.

The necessity for further quality evidence is to be coordinated by the supplier with ALBER's purchasing department.

5.11 In the case of non-European suppliers, for every delivery ALBER requires documented proof that the quality assurance system has had an efficacy audit. This includes in detail the following documents in English:

- material certificate, min 3.1, preferred 3.2
- documentation of interim and final audits upon request.

5.12 Quality problems arising at the supplier or at its sub-suppliers are to be notified to ALBER without undue delay insofar as they pertain to products already delivered or a potential risk for these. This also includes quality problems which might negatively influence further timely delivery. In the case of the quality problems arising which pertain to products already delivered, the supplier shall be obliged to inform ALBER which of the deliveries are or might be affected by the quality problem. In its own interests (limiting the scope), it is suggested that the supplier use a corresponding lot-tracking or even serial-number tracking for this purpose. ALBER hereby reserves the right to demand this in the case of critical parts.

**6. Packaging, good labelling and traceability Delivery date variations**

6.1 The packaging and the labelling of the products must be done pursuant to the processes agreed with ALBER. The deliveries are to be labelled in such a way that the products can be clearly identified at all times. The supplier shall be responsible for the protection of the products supplied by it.

6.2 Traceability with regard to the supplier's production documents must be guaranteed. In general, at least the following details should always be available in this context:

- article number
- serial number (if serial numbers are used)
- drawing or specification number
- product labelling/name
- information on material batches
- supplier labelling
- lot designation (if lots are used)
- manufacture date
- quality information.

6.3 In the event of a quality problem, access to lot and production data for ongoing production orders must be possible within one working day. Access is made within three working days for production orders which have already completed. If a defect occurs with regard to products, it must be ascertainable without undue delay which other products might be affected. In detail, packaging and labelling are to be defined in the product specification and/or supplementary specifications or guidelines.

6.4 Traceability is to be guaranteed via a production control in production lots. A lot corresponds to the goods produced within one continuous production cycle (e.g. production day, shift, etc.) during which no modification of the quality parameters was made. A lot can also be a single medical device or product. Each lot is to be allocated clear designations by the supplier (e.g. lot number).

6.5 Within one production lot, inter alia the following parameters are to be kept constant:

- material type or component type
- process parameters (incl. tools, manufacturing environment within prescribed tolerance ranges).

6.6 In principle, a lot-related system is to be maintained by the supplier for traceability. In addition, ALBER can demand serial number-related traceability if necessary, particularly for critical components. These requirements shall apply in particular also for software in circuit boards in order to identify the software status. If the software status cannot be applied directly to the assembly unit or the component, e.g. due to the size of circuit boards, then another labelling is to be chosen. The supplier shall be obliged to guarantee a version management for software components. Information from such a system is to be made available to the principal upon delivery.

6.7 If the supplier delivers or assembles electronic components and/or assembly units which are susceptible to electrostatic discharge (ESD), the supplier must have an active ESP program and special ESD processing and packaging processes, in which regard the packaging of such products is to be designed in such a way that requirements for protection against ESD are fulfilled thereby. The supplier shall be obliged to keep records about audits and training measures carried out and to present these without undue delay upon request.

6.8 The packaging as well as the packaging material used for the products which are built into ALBER medical devices shall be done pursuant to agreement with ALBER and taking account of the general statutory requirements (e.g. RL 2004/12/EC concerning packaging and packaging waste). Packaging of the products to be manufactured by the supplier is to have the following characteristics

in principle:

- firm and secure packaging
- packaging can be an individual package or collective package
- returnable package is permissible if storage at ALBER can be guaranteed for up to 1 year
- prevention/reduction of electrostatic charging (ESD film or similar)
- prevention of contaminant particles (closed packaging).

6.9 If a consignment consists of more than one package for which the above information is obligatory, the same documentation obligation shall apply also for the entire consignment. It must be accompanied by a document which contains the same information. In detail, the transport packaging is laid down in the respective order or separate agreement for products to be delivered by the supplier to ALBER. Irrespective of this, the supplier shall in general use packaging which effectively prevents contamination, corrosion or damage during manufacture and during transportation of the products to ALBER.

#### 7. Quantity guarantee concept, adherence to the supply lots

7.1 Every product for ALBER must in general be selected by the supplier in such a way that the goods are not damaged or soiled through storage or transportation, and can always be stored optimally.

7.2 If a packaging unit (PU) is given in an order or request by ALBER, then the supplier shall be obliged to ensure that the goods are delivered in the corresponding quantity and packaging. The standard packaging and dimensions of the PUs are:

- (B = plastic box, K = carton box)
- Euro pallet 1200x800x1200mm without protrusion of the goods
- B20 600x400x220mm
- K30/B30 400x300x220mm
- K40/B40 300x200x150mm
- K45 300x110x100mm

7.3 Should it not be possible for the supplier to adhere to the PU, then it shall be obliged to inform ALBER at an early stage about this, and must obtain approval from ALBER before delivery. Otherwise, ALBER hereby reserves the right to reject the goods if applicable, and to invoice the supplier for the transportation and handling costs which have arisen in this context.

7.4 If nothing to the contrary is agreed upon, the supplier is to ensure that the weight of a PU does not exceed 10 kg.

#### 8. Defect prevention

8.1 In order to prevent quality problems arising in connection with serial production, and in order to reduce the requisite inspection work and expense to a minimum, the supplier shall be obliged to carry out analyses of potential defects and their consequences in the form of process and design FMEAs.

8.2 For parts for which the supplier bears the construction responsibility, this is a design FMEA. For all parts with PPA level 3, this shall be required.

8.3 A process FMEA should be carried out by the supplier for all parts, structural components, elements and components, ideally before commencement of the manufacturing of tools and installations. In this context, all of the factors which influence the production process are to be taken into consideration and evaluated. Corresponding precautions regarding process safeguarding must be taken for the weak points identified. For all parts with PPA level 3, this shall be required.

8.4 Upon request by ALBER, inspection of the corresponding FMEAs must be granted by the supplier at any time. As a general rule, this shall take place during the planned supplier audit.

8.5 ALBER hereby reserves the right to demand an FMEA without separate costing to ALBER for certain parts or processes.

#### 9. Defective deliveries

9.1 ALBER requires that the supplier guarantees, by means of a system of controlled processes, incoming-goods checks, SPC measurements and random-sample checks in outgoing goods, the conformity of its deliveries with the agreed ALBER specifications (drawings, in most cases) and other legal requirements (e.g. ROHS, REACH). Should this not be possible, then the supplier hereby un-

dertakes to carry out corresponding other outgoing-goods checks. Irrespective of this, these can also be agreed upon separately for certain, usual product groups (such as electronic assembly units by means of test stations). For incoming goods, ALBER only carries out in addition random-sample checks as well as a visual inspection of the delivery with regard to the delivery quantity, transport damage and/or other obvious defects.

9.2 The supplier hereby agrees that it – subject to the last sentence of Clause 8.1 hereof – waives its rights pursuant to § 377 of the German Commercial Code (HGB). The supplier hereby also agrees that the outgoing-goods check to be carried out by it serves the same purpose as the incoming-goods check really required of ALBER pursuant to § 377 of the HGB. This shall not include complaints with regard to the delivery quantity, transport damage or other obvious defects which can be identified at first glance. The supplier shall ensure that its third-party liability insurance recognises the foregoing amendment to the statutory liability rule, without the existing coverage of its third-party liability insurance being detrimentally affected as a result thereof.

9.3 In the event of defects which ALBER only discovers during assembly, in-line testing, end-of-line testing or in the outgoing-goods check, ALBER shall complain about these without undue delay after discovery (in the named areas of the value chain). This shall also apply for the discovery of hidden defects which only surface as a result of usage in the field, such as (non-exhaustive) impermeability, contact problems or cold solder joints. The supplier hereby waives the defence of late complaints about defects. A complaint commences already upon the sending of the information (defect ticket or 8D report) about a defect.

9.4 Upon the discovery of defects, ALBER will draw up a defect ticket and will return it to the supplier together with the non-conforming goods with debit (i.e. the value of the returned goods will be invoiced for). If necessary, coordination will be done in this respect with the supplier concerning the modalities of the return of the products and/or sorting process or reworking. This process serves a swift and simple complaints handling; the supplier's right to subsequent performance remains unaffected hereby. The supplier can, after approval by ALBER, rework the defective delivery/goods or rectify the defect and redeliver the now flawless goods and invoice for the agreed goods value. The maximum time period for the subsequent performance or the supply of reworked goods is limited to a maximum of 3 months. Reworked goods or subsequent-performance deliveries must be clearly labelled as such by the supplier.

9.5 ALBER demands a swift defect rectification and in serious cases an 8D report about the defect rectification measures within 10 working days in order to effectively prevent recurrence.

9.6 In exceptional cases - taking account of costs, deadlines and capacities – approval of the products complained about can take place by means of limited special approval. In this respect, ALBER hereby reserves the right to pass on the costs arising as a result thereof to the supplier, such as

- sorting costs
- repackaging costs
- subsequent-delivery costs
- reworking costs
- inspection costs, internal and external
- any costs regarding special approvals
- special shifts
- transportation and logistics costs in connection with actions in the field (recall, field correction).

A processing fee in the amount of EUR 50 (as of 2012) shall be charged for the internal inspection, insofar as no higher costs arise and are demonstrable, for each quality incident for which the supplier is to blame.

9.7 ALBER shall have no further obligations to the supplier than the foregoing checks, inspections and notifications.

#### 10. Special approvals

10.1 The supplier has the possibility of asking ALBER for a special approval before delivering the goods for defects discovered at its company. Approval is given in terms of piece numbers and/or time period. A special approval granted once shall not entitle the supplier to deliver parts with this deviation in the event of recurrence.

10.2 ALBER hereby reserves the right to reject these if there is an accumulation of requests for special approval for a certain characteristic. For every request for special approval, a written statement with measures is to be sent by ALBER. Deliveries are definitely to be labelled accordingly, bearing the special approval on the goods and the delivery papers.

#### 11. Maintenance of tools, equipment

The supplier shall bear the costs of ongoing maintenance, necessary repairs of the tools as well as all aids which are necessary for the manufacture of the tools; this work is to be carried out continuously by the supplier. The determination of the scope and the intervals for the maintenance shall be incumbent upon the supplier. The tools, equipment, etc. must continuously be in a faultless condition ready for production, so that the supplier is able to produce at any time. This shall apply for tools owned by the supplier and owned (including partially) by ALBER. Arrangements stating otherwise are possible and shall remain unaffected hereby.

#### 12. Labelling of the tools

The supplier shall clearly label the tools and equipment owned by ALBER, and/or the tools and equipment acquired/set up by the supplier expressly for its work for ALBER which are owned by the supplier but are nonetheless financed by ALBER via the remuneration agreed upon between ALBER and the supplier, by affixing a sign or identification plate with the following details:

- property of ALBER GmbH (if ALBER owns it)
- customer ALBER GmbH (if the supplier is the owner)
- article number and/or drawing number
- part designation
- manufacture date and weight of the tool or equipment
- tool number and/or storage location (pursuant to the supplier's system).

#### 13. Special statutory requirements

13.1 The supplier hereby undertakes to comply with all of the statutory requirements pertaining to the products supplied. The following are to be complied with in particular (list is not exhaustive):

- ROHS
- REACH
- the German Battery Act (BattG)
- the German Packaging Ordinance (VerpackVO)
- transportation provisions for deliveries by the supplier to ALBER.

13.2 Amendments to these sets of rules (and co-applicable documents such as the SVHC list of REACH) shall be monitored and taken into account by the supplier. The supplier shall inform ALBER without undue delay about these. This shall also apply for new or previously unknown statutory or normative requirements which the supplier becomes aware of.

13.3 ALBER hereby reserves the right to pass on to the supplier monetary fines, criminal penalty payments or recourse claims due to breaches of applicable law which are the supplier's fault.

#### 14. Documentation obligations

14.1 The supplier shall be obliged to define business, production-related and quality-assuring processes and measures (e.g. testing plans) with regard to the respective products to be supplied by it. The supplier shall be obliged to inform ALBER about these testing plans and to keep records about the implementation of these testing plans in sufficient scope and in a demonstrable manner.

14.2 Quality records shall serve to prove that quality requirements have been fulfilled and that a quality assurance system which is present is functioning effectively. The supplier shall be obliged to keep all quality records and any associated samples, templates and specification documents (specifications, drawings, working and testing plans, testing records, etc.), in a clear and orderly manner, for a period of at least 10 (ten) years after the last delivery to ALBER, or to third parties named by ALBER, of the product to be developed and/or to be produced. ALBER shall be informed by the supplier about the imminent destruction after the expiry of the archiving period.

14.3 The supplier shall permit ALBER inspection in the necessary scope and hand over copies of records as well as any samples and templates upon request. If the supplier intends to modify testing plans for a product defined by ALBER by means of supplier specification, then it shall be obliged to inform ALBER without undue delay about the

intended modification.

14.4 Upon request by ALBER, all of the documents and quality records associated with products manufactured for ALBER can be inspected by ALBER at the supplier (e.g. in the framework of a supplier audit).

14.5 Documents and records regarding the creation of ALBER-specific products must be capable of being made available continuously and without limitation, including from the sub-suppliers involved, at short notice in paper form or as a data file.

14.6 The supplier shall be obliged to carry out and to document all manufacturing steps including incoming-goods checks and other quality checks as well as approvals (materials, components, products) in accordance with the rules of good documentation practice.

#### 15. Contract term, termination

15.1 This Agreement shall enter into force upon the granting of the supply contract. The term is unlimited. The Agreement can be terminated by either of the two contract partners in compliance with a notice period of six (6) months.

15.2 The partners' right to effect termination without notice for an important reason shall remain unaffected.

15.3 Termination of this Agreement shall entitle ALBER to effect extraordinary termination of some or all of the contracts affected by this QAA which concern the delivery of goods or the rendering of services. The termination of such contracts shall come into effect simultaneously upon the termination of the QAA.

15.4 In any event, the obligations to store the documentation as well as the obligations to cooperate in the clarification of notification-subject events pursuant to the German Medical Devices Act and Directives 93/42/ECC and 98/79/EC shall remain unaffected by the termination.

#### 16. Final provisions

16.1 Amendments or additions to these standards shall require the written form. This shall also apply for any deviation from this written-form clause.

16.2 Should a provision of these standards be or become invalid, then the rest of the standards shall not be affected thereby and shall remain valid. The parties hereby undertake to replace the invalid provision with a provision which comes closest to the financial purpose of the invalid provision. The same shall apply in the event that a provision transpires to be unfeasible, or should it transpire that the standards contain unintended lacunae.

16.3 The contract relationship shall be governed by German law, and the application of the UN Convention on Contracts for the International Sale of Goods (CISG) is hereby excluded.

16.4 The legal venue for all disputes in connection with these standards shall be Albstadt. However, ALBER shall be entitled to sue the supplier in another court with jurisdiction as well.