FOBA®
*Laser at your service*

# Company Data and Quality Management Self Assessment

## Frequently Asked Questions about ALLTEC/FOBA as a Supplier

*During the acquisition process of a new FOBA laser system, one of the documents you ask our customer support for is a supplier self assessment. The following list provides you with the most important company information you may need.*

## Company Information

### Address, Contacts, County Court

ALLTEC Angewandte Laserlicht Technologie Gesellschaft mit beschränkter Haftung
An der Trave 27 - 31 | 23923 Selmsdorf | Germany
Managing Directors: Sebastian Bloesch, Peter Fuchs
Tel. +49(0)38823 55-0
Website: https://www.fobalaser.com | E-Mail: info@fobalaser.com
Local Court: Schwerin HRB 7884

### Organizational Information

Founded: 1985
Employees: >200
Mother Company: Danaher Inc.

### Tax Numbers

☐ VAT No.: DE 135074115
☐ Tax No.: 079/133/02316
☐ DUNS No.: 34-134 0672
☐ WEEE-Reg.-Nr.: DE 92613462

### Bank Account

☐ Bank Address: Deutsche Bank AG, Unter den Linden 13/15, 10117 Berlin
☐ Bank account No. 167 397 900
☐ Bank code 100 700 00
☐ Swift code DEUTDEBBXXX
☐ IBAN DE 75 1007 0000 0167 3979 00

### Portfolio/Business Operations

☐ Laser marking systems, spare parts and related software
☐ Development and manufacturing of innovative laser marking and engraving machines
☐ Customised laser marking systems for OEM and integrators
☐ Vision-inspection systems for part validation, mark alignment, and post-mark validation/verification

### Certifications

☐ ISO 9001:2015, Reg. No. 01 100 020455
☐ AEO C

As supplier to medical device manufacturers, ALLTEC seeks to comply with parts of the following standards:
☐ 21 CFR 820
☐ ISO 13485:2003
☐ ISO 17025:2005

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# Quality Management

## Quality Management System (according to EN ISO 9001:2015)

☐ ALLTEC/FOBA Quality Policy: "We are committed to providing the best solutions for laser-based marking and engraving and the best service for our customers."
☐ ALLTEC/FOBA has a Quality Management System (QMS) in place which is certified according to ISO 9001:2015 (first certification 2002, current certification expires 2019).
☐ ALLTEC/FOBA is commited to the over all Danaher policies and established its own market-specific quality policy.
☐ The structure of ALLTEC/FOBA's QMS is process-oriented and includes three different process categories: Management, Core and Support processes.
☐ All processes are documented in a Quality Management Handbook (QMH). The QMH is maintained by the Quality Management Representative. Each individual process has its defined owner who is responsible for the implementation of all process requirements.

## Change Control (according to EN ISO 9001:2015 8.5.6)

☐ ALLTEC/FOBA has a documented change control process.
☐ The change control process does not include notifications to individual customers.

## Document Controls (according to EN ISO 9001:2015 7.5, ISO 13485:2003 Sections 4.2.3 and 4.2.4 – 21 CFR Part 820.40, ISO 17025:2005 Section 4.3, 5.4.7)

☐ ALLTEC/FOBA has a document control system in place. All processes and related forms documented in the Quality Management Handbook are controlled documents under the responsibility of the Quality Management Representitive. They undergo a review and approval process before release.
☐ All controlled documents include creation, change, approval and release dates to permanently ensure the use of the current version. Revision control also applies to all drawings, specifications and standard operation procedures (SOPs).
☐ ALLTEC/FOBA has a process in place to handle updates to standards and norms. Third party specifications and drawings are referred to including revisions and or dates.
☐ Obsolete process descriptions are stored in archive folders.
☐ Validity period of documents is not restricted.

## Process Validation (according to EN ISO 9001:2015, ISO 13485:2003 Section 7.5.2 – 21 CFR Part 820.75 – ISO 17025:2005 Section 5.4.5)

☐ For all production processes ALLTEC/FOBA conducts FMEAs in order to proactively detect possible process failures and adjusts the processes before release. These FMEAs are updated as needed, e.g. during change process.
☐ Production processes are validated by beta builds of products as mandatory part of the development process. Results of these above activities are captured in the product main files.

## Corrective & Preventive Action (according to EN ISO 9001:2015 8.7 & 10.2, ISO 13485:2003 Section 8.5 – 21 CFR Part 820.100 - ISO 17025:2005 Section 4.1.1)

☐ ALLTEC/FOBA as being part of the Danaher Corporation is an indicator driven company. Metrics to measure performance, quality and effectiveness are applied at all levels of the business.
☐ ALLTEC/FOBA and Danaher maintain a system of corrective and preventive measures at all levels of the business. Starting at the shop floor level, issues are pin-pointed and solved in daily management. Larger issues are covered by a company wide 'Problem Solving Process', a tool which includes different levels of paretos, 5why-analysis, countermeasure and sustainment actions with defined responsibilities and due dates.

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**Quality Records and Retention (according to EN ISO 9001:2015 7.5, ISO 13485:2003 Sec. 4.2.3 & 4.2.4 – 21 CFR Part 820.181, 820.184, & 820.186, ISO 17025:2005 Sec. 4.4, 4.8, 4.13, 5.4.7, 5.17)**

☐ Records of each individual product are maintained in a product data base. These include bills of material, final test results, installation records as well as later service case records and complaints.
☐ ALLTEC/FOBA uses a database system software to track all transactions with systems after installation. Required information is entered into mandatory fields. Thus all necessary information is on hand when needed.

**Quality Audits (according to EN ISO 9001:2015 9.2, ISO 13485:2003 Section 8.2.2 – 21 CFR Part 820.22 - ISO 17025:2005 Section 4.14)**

☐ ALLTEC/FOBA maintains a regular quality audit program for processes and products. A yearly audit schedule is used to schedule these audits. Additional quality audits can be scheduled as needed.
☐ All audit findings are documented, countermeasures are followed-up and sustained by action plans added to the audit records.

**Statistical Techniques (according to EN ISO 9001:2015 9.1.3, ISO 13485:2003 Section 8.1 – 21 CFR Part 820.250 - ISO 17025:2005 Sections 4.6, 5.7)**

☐ Key indicators are captured and tracked at all levels of production. Statistics with these data are drawn as needed.

## Operations / Manufacturing

**Production & Process Controls (according to ISO 13485:2003 Sections 7.5 and 7.5.2 – 21 CFR Part 820.70 - ISO 17025:2005 Section 5.3)**

☐ Each product undergoes a final inspection with product specific test steps.
☐ Changes to design or specifications are initiated via change requests and evaluated by the change control board. As soon as change requests are approved, they undergo a defined maintenance of line process and finally are implemented into the ERP system.
☐ The production process of each product is described in standard operator procedures (SOP). The build progress for each product is recorded in the production traveler and final inspection results are recorded in test protocols in the systems database.
☐ Key indicators are captured and evaluated at all levels of production.

**Preventive Maintenance**

☐ Each production cell controls its equipment on its own. In course of visual management maintenance schedules including pass, fail and countermeasures for equipment is displayed at every equipment needing maintenance. The adherence to the schedule is observed during regular internal audits.
☐ Material aging over time is equipped with best-before date-marks. The renewal of aging material is observed in regular internal audits.

**Inspection, Measuring, and Test Equipment (according to EN ISO 9001:2015 7.1.5.2, ISO 13485:2003 Section 7.6 – 21 CFR Part 820.72 - ISO 17025:2005 Section 5.4, 5.5, 5.6, 5.9)**

☐ Measuring devices are monitored with a database system holding datasheets and calibration records for all devices.
☐ The database system is reminding the measuring device responsible of upcomming calibration dates.
☐ Calibration for all measuring devices is perfomed externally by certified calibration labs.

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**Handling, Storage & Distribution**
**(according to ISO 13485:2003 Section 7.5.5 – 21 CFR Part 820.150 and 820.160 - ISO 17025:2005 Section 5.8.4)**

☐ Material is stored in a two bin Kanban system close to the production areas. The Kanban system assures a FiFo consumption and replenishment of the inventory. Inventory level and turns both are key perfomance indictors (KPI) for operations and reviewed on a daily basis.
☐ Obsolete parts are sorted out during the process of implementing new revisions. Rejected, damaged or deteriorated material is separated in a restricted area, labeled with red tags and reprocessed or scraped.

**Nonconforming Material**
**(according to ISO 13485:2003 Section 8.3 – 21 CFR Part 820.90 - ISO 17025:2005 Section 4.9)**

☐ ALLTEC/FOBA performs a PPAP process called 'First Article Inspection, FAI' before releasing supplier delivered parts and assemblies to production. For each specific part supplier and inspection cycles are monitored.
☐ In case of non-conforming parts or assemblies these are segregated in a dedicated area together with a failure report and rejected to the supplier.
☐ For reaccuring non-conformance the Danaher PSP process is applied which includes 5why analysis and leads to corrective actions and sustainment after implementation.
☐ ALLTEC/FOBA requires RoHS compliance certificates for all delivered parts and materials.

**Nonconforming Products (according to EN ISO 9001:2015 8.7,**
**ISO 13485:2003 Section 8.3 – 21 CFR Part 820.90 - ISO 17025:2005 Section 4.9)**

☐ Each product undergoes a final inspection with product specific test steps. Since ALLTEC/FOBA products are complex products they are not disposed in case of failure. The failure is being analysed and products are reworked as needed and fully retested. The incidence of failing final inspection is recorded and captured in a KPI called First Pass Yield.
☐ As part of the development process design- and process FMEAs are conducted to proactively capture possible process failures. Moreover an appropriate number of beta systems are built and manufacturing quality tests are performed in order to observe building, testing and shipping procedures before launching new products.
☐ After delivery the products are being installed and evaluated together with the customer. In case of any failures these are repaired either at the customer site or in very rare cases transfered back the the manufacturing site.

**Labeling and Shipping**

☐ Products (except for some spare parts) are identified by serial number. The serial number including the shipping bill is displayed outside of the box.
☐ ALLTEC/FOBA uses a specialized packaging service supplier. All packages need to pass ISTA tests before being accepted.

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## Purchasing / Reviewing

**Purchasing Controls/Contract Review**
**(according to ISO 13485:2003 Sec. 7.2.1, 7.2.2, & 7.4 – 21 CFR Part 820.50 - ISO 17025:2005 Sec. 4.4, 4.5, 4.6, 4.7)**

☐ The ALLTEC/FOBA Supplier Quality Management (SQM) process is part and in line with the Danaher Reliability System (DRS). The SQM includes processes for supplier selection, performance measurement and development.
☐ Supplier selection includes self assessment and initial supplier audits among others. Performance measurements base on performance indicators like quality, cost and delivery.
☐ Supplier development includes training and developing suppliers and their associates to the desired level of performance.

**Identification & Traceability (according to EN ISO 9001:2015 8.5.2,**
**ISO 13485:2003 Section 7.5.3 – 21 CFR Part 820.60 and 820.65 - ISO 17025:2005 Section 5.6, 5.8.2)**

☐ Each laser marking system is identified by an unique serial number.
☐ The serial number is established before the manufacturing process and identifies each product throughout production.
☐ The serial number is used to identify and trace the product throughout its whole lifetime.

## R & D: Software Development

**Process Controls**

☐ Our Software development process is one of our core processes controlled within our ISO 9001 certified quality manual.
☐ Using the Danaher Software System, including the Danaher processes LSD (Lean Software Development), PRTI (Personal Review and Team Inspection) and SPA (Software Process Automation), all aspects of the software development are guided and under survey.

**Change and lifecycle management**

☐ Software changes or new functionalities are controlled within the DDS (Danaher Development System) and the APD (Accelerated Product Development) process. From the initial feasibility check, the technical and risk analysis over to actual planning, realization, launch and runtime, all steps and sub steps are monitored and reviewed during the whole software life cycle.
☐ Risk and classification analysis are part of the Danaher APD (Accelerated Product Development). A triaging system is controlling risks of each individual change.
☐ Within our Danaher Business System, requirements and changes as well as new functionalities are tracked and reviewed.

**Tools**

☐ Associating our Danaher software processes, we are using a well-orchestrated tool set for all aspects of our daily work and the software life cycle.
☐ The Atlassian toolset including Jira, Bamboo, Crucible and Confluence is implemented to control daily workflows, coordinate software sprints, document and automatically test any kind of software changes.
☐ Coding standards, static code analysis and in-code documentation help us to maintain and improve existing and new software elements.
☐ A version control system is used to track and protect our codebase and gives a rigorous control over all changes done to the software.

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## After Sales: Service and Support

### Installation

☐ With every delivery, ALLTEC/FOBA provides a customer manual, including safety instructions as well as installation and maintenance FAQ.
☐ Documents are available in the languages German, English, French, Spanish, Italian, Portuguese, Chinese, Dutch, Czech, Polish, Slovenian, Lithuanian, Romanian, Hungarian, Danish.

### Maintenance

☐ For every product and option, a dedicated maintenance procedure and protocol is available.
☐ We provide additional maintenance steps and separate protocol for MQ to meet IQ/OQ customer needs.
☐ Annual maintenance or maintenance on demand options, based on committed service-contract.

### Service Support

☐ 24/6 Hotline support and call-acceptance, worldwide availability
☐ Cloud-based FOBA Remote Service program for both pro-active service support and predictive maintenance
☐ First step approach aiming at immediate remote support, before scheduling onsite intervention.
☐ All cases will be recorded into our case management system to have a clear view and error history.

### Spare-Parts Order

☐ Dedicated listing of spare-parts and customer recommendation for on-site-stock available upon request.

### Engineer Training

☐ In-house-training and certification of trainers at tollgate process 4 by R&D engineers.
☐ In-house-training and certification of engineers at tollgate process 5 by trainers and R&D

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