SUPPLIER HANDBOOK

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1 Introduction

1.1 Background and objectives of this Handbook

STRATEC SE and its affiliates ("the companies" or "STRATEC") contribute to their partners' success around the world with their top-of-the-range medical-technical products. In this context, the quality of supplier components is crucial to the quality of our highly technological end products, which are used in the healthcare sector for diagnosis and prevention as well as in the research and development of new technologies, thereby contributing to the continuous improvement of our quality of life.

Global competition, continuing advancements in the research and development of new procedures and processes, and our commitment to production methods that are gentle on the environment and natural resources demand high flexibility and short reaction times from us as well as from our suppliers, along with the willingness to embrace the steady, cost-effective development and optimization of products and business processes.

We aspire to always be one step ahead of our customers' steadily increasing demands and desires. In order to accomplish this goal, we limit ourselves to our core competencies in the area of analysis systems. Because we restrict ourselves to high-level assembling and final testing, along with design and development, the depth of value added lies with our suppliers. This requires strategic partnerships with competent system suppliers in the area of high-mix, low-volume production. Therefore, the willingness to take responsibility for the processes and technologies required to manufacture the product is the foundation for successful, effective cooperation.

This Handbook describes fundamental, STRATEC-specific requirements and guidelines and offers existing and future suppliers the possibility of being one step ahead of our requirements – right from the start.

1.2 Vision • Mission • Guiding Principle

As an innovative and technological market leader for automation and instrumentation solutions in in vitro diagnostics, we aspire to offer our partners around the world first-class solutions through which we share responsibility for their customers and patients.

Our partnerships are built on mutual trust, continuity and professionalism. Our common mission is to develop safe, innovative and market-leading products that meet our customers' expectations at all times. For STRATEC, partnership means responsibility, passion and a commitment to our customers and products that go far beyond the end of a product life cycle.

For our suppliers, partnership with STRATEC means in-depth involvement in complex development projects and access to the latest technologies. Long project periods, intensive cooperation and the status of a "specialist" give our suppliers a reliable basis for long-term planning and enable them to expand their product portfolio and tap into new markets and business fields.

1.3 Scope of application of this Handbook

This Handbook applies to all suppliers of STRATEC, in particular to suppliers of production goods and services. However, the requirements described must be considered in the context of each individual supplier.

2 General requirements for our suppliers

2.1 General requirements

A mutual, successful business relationship depends on the general willingness to comply with the arrangements described below. Because the complexity of our products requires them to be produced in an early development stage and continuously perfected, we expect our suppliers to exhibit commitment to and active cooperation in the realization of optimally manufactured and therefore cost-effective solutions, as well as high flexibility in regard to changes and fluctuations in demand. Only in this way can we successfully manufacture our sophisticated products and satisfy our customers' high expectations. Our suppliers' competence, experience and commitment enable us to even surpass these expectations.

The requirements and guidelines described in this Handbook should be understood as minimum requirements and complement all other contractual agreements between the supplier and STRATEC. They do not replace any requirements of DIN EN ISO 9001, DIN EN ISO 13485 or any standards used in documents related to this Handbook, nor any statutory requirements.

2.1.1 Insurance coverage

Depending on the relevant business area, the supplier undertakes to take out sufficient insurance with an adequate level of coverage. In this regard, we refer to the Basic Agreement or the General Terms and Conditions of Purchase.

2.1.2 Contingency management

By preparing contingency plans, the supplier ensures that all required products and/or services are available in the ordered quantity, free from defects and in due time, including in the event of extraordinary incidents such as production standstill due to breakdown of production facilities, strike or personnel unavailability otherwise caused, or limited delivery capability of sub-suppliers. Examples include, among others:

- Maintaining alternative production facilities
- Appropriate personnel planning (qualification matrix)
- Flexible working hours
- Buffer stocks
- Alternative sub-suppliers

2.1.3 General Terms and Conditions of Purchase (“GTCP”)

When a business relationship is entered into, orders and deliveries are generally made in accordance with our GTCP. These can be accessed at https://www.stratec.com/supplier?file=files/inhalte/Supplier/General%20Purchase%20Conditions_June%202020.pdf&cid=2026

2.1.4 Code of Conduct (“CoC”)

Our CoC contains and defines principles and requirements for our suppliers regarding their responsibility for people and the environment.

2.1.5 Continuous Improvement Process (“CIP”)

Our suppliers undertake to continuously improve the products and services delivered to STRATEC and all activities connected with the business relationship. They ensure this through appropriate procedures and measures and demonstrate their effectiveness through constant performance improvements in quality, delivery practices, pricing, cost reduction, flexibility and cooperation.

We expect the individual cost advantages to be passed on unrequested to STRATEC no later than upon conclusion of a new Basic Call Agreement. The corresponding measures and programs for continuous improvement are to be submitted to STRATEC on request.

2.1.6 Responsibility of the supplier

Because of the shallow depth of value added, the quality of our products is directly determined by the quality of the supplied components and modules. Because we have made a pledge to our customers to pursue a zero-error philosophy, we expect this from our suppliers as well. In order to achieve this goal, our suppliers ensure that process and product risks across the entire value-added and supply chain are identified already during the planning stage, that effective measures to prevent or detect possible errors are developed and that they are documented within their QM system.

Accordingly, the complexity of our products and the demanding requirements for the individual components require comprehensive and proactive quality management, open communication within a clearly defined, unbroken information chain and the readiness to continuously optimize the entire process landscape. In this context, the supplier identifies and analyzes possible potential for improvement and realizes it through corresponding measures. Where appropriate, this may require prior approval by STRATEC.

2.1.7 Certification / QM system

In order to ensure quality-capable processes, the supplier uses an effective quality management system and demonstrates its effectiveness.
Its effectiveness can be demonstrated by:

- a valid certificate under DIN EN ISO 9001 and/or DIN EN ISO 13485, issued by an accredited certification agency
  or
- a QM system audit by STRATEC
  or
- written documentation of an established QM system.

2.2 Compliance with legal requirements

Our suppliers undertake to comply with all legal requirements, regulations and norms (including technical norms) that are relevant for the safety of the product to be delivered in general, for the service to be performed and for delivery to STRATEC. The applicable legal requirements and relevant standards apply as minimum requirements even when not specifically referred to in an individual case. In case of doubt, the acknowledged state of science and technology applies.

Examples:

- RoHS, REACH
- Environmental regulations
- Long-term supplier’s declaration
- Good Manufacturing Practice (“GMP”)
- Good Documentation Practice (“GDP”)
- Occupational safety and health protection
- Requirements related to customs and foreign trade regulations

2.2.1 Long-term supplier's declaration ("LTSD")

We generally require our suppliers to make a long-term supplier's declaration in accordance with the relevant EC regulation. Where necessary, the supplier receives from us an appropriately prepared form sheet and undertakes to verify, supplement, correct where necessary and sign it. The retention periods (3 years and 6 years) must be observed.

2.2.2 Retention regulations for documents

The supplier and its sub-suppliers retain for 15 years all original documents necessary to trace the manufacturing process such as maintenance plans, process and setting parameters, material testing certificates or proof of material compositions, special releases and rework instructions.
Further details are described in the STRATEC quality assurance agreement (QAA).

3 Strategic supplier management

3.1 Objectives

- Cost reduction
- Quality improvement
- Integration and further development
- Increasing competitiveness
- Ensuring supplies of materials

3.1.1 Early involvement in the development process

In order to make use of synergy effects, the qualification of new suppliers takes place at an early development stage. The aim is to find both innovative and cost-effective solutions that are jointly developed in the lead-up to the final technical specification.
The systematic design, control and further development of the cooperation must also be seen in this context. This includes measures such as the transfer of expertise and the training of the supplier's personnel. This development process is continuously monitored during the entire term of the project. Where necessary, process optimization measures are carried out with the goal of achieving cooperation that is profitable, growth-oriented and successful for both sides.

3.1.2 Securing the supply chain

The suppliers are responsible for securing their own supply chain. They adopt appropriate measures so that the supply of parts by their upstream suppliers is secured. This also applies to upstream suppliers prescribed by STRATEC.

3.1.3 Securing delivery capability

Our suppliers' delivery capability is of utmost priority because of the number of required components and the complexity of our devices. In order to ensure the availability of parts, our suppliers must therefore consider the following measures:

- Buffer stocks (supplier's own or sub-supplier's)
- Minimum supplies (of manufactured goods, raw materials and purchased parts)
- Contingency plans (e.g. in case of insolvency or production standstill otherwise caused)
- Basic Agreements
- Optimization of batch sizes and delivery times
- Ownership and management of tools
- Second source
- Systematic screening of suppliers at risk

The security of delivery capability is verified

- by way of supplier assessment
- where appropriate, in the context of audits

3.1.4 Ensuring quality

All delivered products must meet previously defined quality requirements. These requirements are defined by us if the product is constructed by STRATEC, and by the supplier if it is a development by a supplier. The quality requirements are described with the aid of specifications, datasheets, parts lists, drawings and/or assembly instructions, among others. The supplier is responsible for meeting these quality requirements.

3.1.5 Verification of the documentation made available by STRATEC

The supplier will verify without delay whether the documents and descriptions made available by STRATEC are patently defective, unclear, incomplete or patently incorrect. If the supplier identifies any of the above, they will alert STRATEC of this deficiency immediately.

3.1.6 Identifying the need for optimization and improvement

The supplier is responsible for using effective systems for monitoring and continuously improving the process and product quality, which includes detecting errors, evaluating error statistics and identifying corrective measures.

3.1.7 Process optimization

As the owner of the process, the supplier ensures that all measures required to safeguard the production process are adopted. If the supplier identifies any deviations before or during manufacturing of the product or during and after testing of the product, the supplier will analyze the cause of the error and take necessary corrective measures to prevent errors from occurring. Corrective measures that directly affect the specifications and/or manufacturing regulations require the approval of STRATEC prior to implementation. The supplier takes care only to process parts that are verifiably free from errors or defects.
STRATEC must be informed immediately if an anomaly in the product function has been detected that poses a threat of danger to life or limb or an increased risk of causing material damage. In such an event, STRATEC assists in the analysis of causes where possible and practical.

3.1.8 Management of sub-suppliers

If suppliers receive upstream supplies, they must satisfy themselves of the effectiveness of the upstream supplier's QM system (for instance through supplier assessments, audits and/or proof of certification) and include them in their QM system as per this Handbook.

Every supplier is responsible for

- ensuring that all products and services the supplier acquires from upstream suppliers and uses for STRATEC products comply with the STRATEC specifications
- acquiring products and services from upstream suppliers who
  - are able to evidence a certified QM system, or
  - are audited by the supplier

- verifying compliance with the quality requirements through incoming goods inspection

A supplier must give timely notification of their intention to replace a sub-supplier.

In justified cases, suppliers enable STRATEC to audit their sub-suppliers within six weeks after receiving a request.

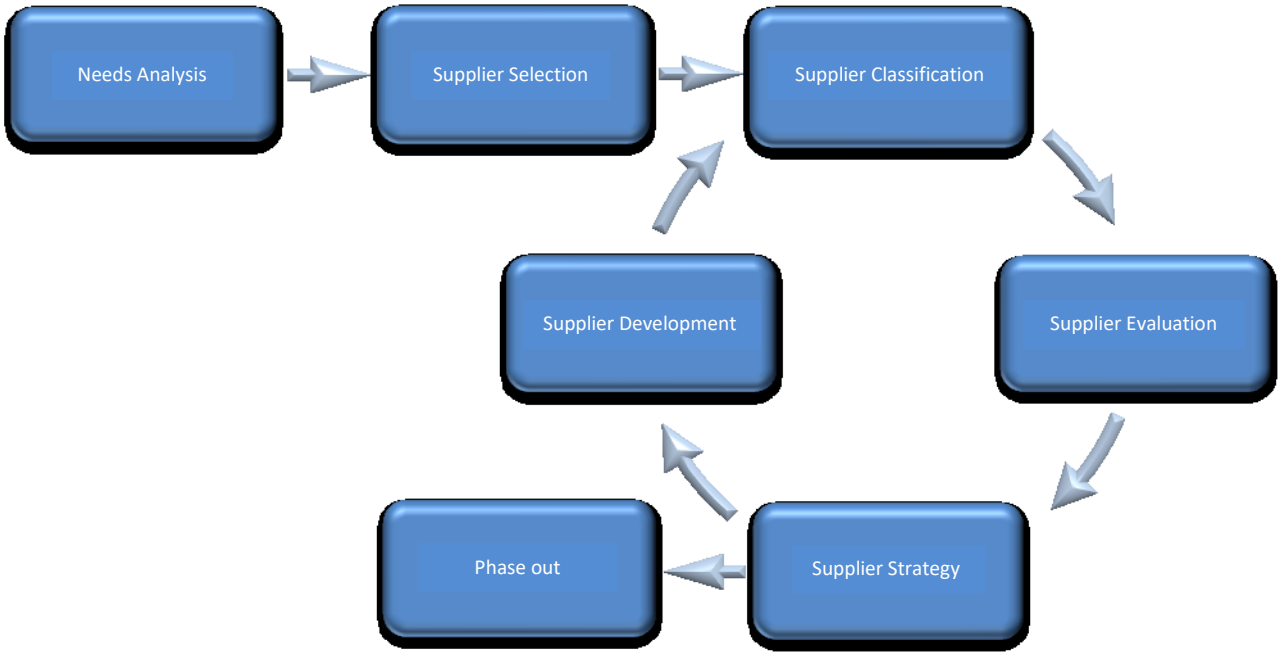
3.1.8.1 Changes in products / services

Suppliers are required to inform STRATEC without delay of any changes made by the suppliers or their sub-suppliers to the products and/or services to be delivered by them. In so doing, suppliers must ensure that they, in turn, receive notification of any changes from their sub-suppliers. STRATEC must agree to such changes in writing before they are introduced.

3.2 Supplier selection process and criteria

Supplier selection is made on the basis of appropriate business plans and needs assessments. For this purpose, we will first determine whether an already approved supplier from the existing portfolio of suppliers can be commissioned or whether a new supplier must be certified. Certification may be necessary because of new technologies, increased demand, changed production processes, new projects or to ensure shipment (second source).

3.2.1 Phases of the process / control loop



3.3 Supplier certification

The desire for continuous improvement and growing demands on us and our products also requires exceptional performances on the part of our suppliers.
To avoid loss of synergies in the achievement of common goals, we must ensure from the outset that our suppliers are able to meet the demands placed on them. This requires a structured and systematic approach to selecting and positioning as well as a need- and performance-based integration of respective suppliers into our company. Key criteria are quality of cooperation, specific performance capacity and the strategic importance of the supplier.
The cooperation period will be marked by a continuous adjustment of expectations and goals. Depending on long-term orientation, project status and needs, additional options for enhancing the collaboration or a scheduled phase-out will be jointly discussed.

3.3.1 Individual specifications

Depending on the supply portfolio, we place different demands on our suppliers. As a result, certain conditions must be met prior to collaborating. The (individual) conditions are described below.

3.3.1.1 Certificate

Proof of a QM (Quality Management) system in accordance with DIN EN ISO 13485 or DIN EN ISO 9001 in the currently valid version.

3.3.1.2 Supplier self-reporting (“SR”)

Regular self-reporting on the part of suppliers will help us to further develop our business relationship. The specific disclosures will provide us with valuable information regarding sales performance, scope of services, and business and technology developments on the part of our suppliers. This allows for targeted, efficient and demand-oriented queries. Based on the number of employees, existing business areas and experience with technologies, further requests can be developed and existing potential leveraged, all combining to strengthen the business relationship. All information will be treated confidentially. Suppliers will self-report every year or every other year as part of their certification and, beyond that, as based on the category of goods.

3.3.1.3 Confidentiality Agreement (“CA”)

With this contractual agreement, both parties undertake to treat as confidential and not disclose to third parties any processes, technologies, developments, information and data associated with the respective contractual partner. In turn, the supplier undertakes to ensure confidentiality through contractual means when involving additional partners.

3.3.1.4 Supplier visitations

In the course of supplier certification, STRATEC conducts supplier visitations. These visits are designed for STRATEC to become acquainted with the company and to make an initial assessment of the supplier’s organization and performance capacity. The result will be documented in an inspection report, which is subsequently evaluated. Supplier visitations take place independently of possible audits.

3.3.1.5 Audits

Supplier audits are intended to ensure that all requirements of STRATEC products and processes that have been outsourced by STRATEC are understood, implemented and properly managed. In particular, this includes the handling and storage of parts and materials, manufacturing equipment and processes, and process documentation. Another goal is the identification of improvement potential for process and product optimization. The review will take place in the form of a process audit.
Further details are described in the STRATEC QAA.

3.3.1.6 Basic Agreement

If necessary, a Basic Agreement will be concluded providing the basis for orders and delivery schedules.

3.3.1.7 Quality Assurance Agreement (“QAA”)

In addition to our General Terms and Conditions and/or the Basic Agreement, the QAA sets forth all requirements to eliminate quality problems and ensure expected product safety.

3.4 Supplier classification

Contingent on groups of goods, sales, delivery and manufacturing process, the supplier receives an internal classification, which is regularly reviewed and adjusted as necessary. This grouping allows for optimal positioning tailored to demand and supplier support.

3.5 Supplier status

If suppliers fulfill the respective conditions, they will be gradually approved in the course of the certification as follows.

- approved for inquiries
- conditionally approved (only for sample and prototype parts)
- approved (for serial parts)

3.6 Supplier Assessment

The fulfillment of STRATEC-specific requirements for the supplier's organization and quality processes is a prerequisite for a successful partnership. Therefore, the assessment of performance capacity in terms of specified requirements is an important component in the qualification of new suppliers and will take the form of supplier visitations and audits. At that point, the measures required for approval shall be defined.

3.7 Supplier Evaluation

To ensure availability of parts, level of quality and supplier education, supplier evaluations are carried out. The evaluation is based on various parameters. In case of development potential, appropriate measures will be derived from the result of this evaluation and communicated to the supplier.

3.7.1 Evaluation criteria

The evaluation is carried out in two categories:

- Quality
- Delivery performance.

3.7.2 Evaluation scheme

According to the evaluation, suppliers can be classified into three groups:

- Group 1 → no measures necessary
- Group 2 → on monitoring, measures optional
- Group 3 → measures necessary

3.8 Supplier development program

3.8.1 Reasons for supplier development

- Quality level
- Audit results
- Supplier self-reporting
- Result of supplier evaluation

3.8.2 Objectives of supplier development

- Cost optimization on both sides
- optimal use of supplier expertise
- Improvement of quality, reliability and effectiveness
- profitable, growth-oriented and successful cooperation

3.8.3 Possible measures

- Blocking
- Supplier audits
- Discussions with suppliers
- Developing an action plan
- Expanding business relationship

- Terminating cooperation

3.9 Blocking

Under certain conditions, suppliers will be blocked. The reasons for this are, among others, audit and visitation results, results of supplier evaluations, quality defects or other contract violations. There are three different types of blocking.

- Partial blocking: Orders and deliveries proceed unchanged. Supplier is only blocked for follow-up projects and other requests.

- Article blocking: Individual articles of the supplier are blocked. For the articles in question, no further purchase orders will be placed.

- Full blocking: The business relationship is terminated.

3.10 Terminating cooperation

To achieve our goals of strategic supplier management as well as to ensure the supply of materials, increase competitiveness, reduce costs, bundle suppliers, but also in the event a product is discontinued, for quality reasons or because of supplier evaluations, it is occasionally unavoidable that a relationship with a supplier be terminated. However, this may only be done through strategic phasing out over a period of time that is long enough for both sides.

3.10.1 Strategic phasing out

This means that both sides will jointly prepare the planning for the appropriate quantities and the associated scheduling, taking into account delivery supply, and monitor it until the business relationship is terminated.

4 Operational supplier management

For the purpose of devising clear criteria of strategic supplier management, such as clearly structuring the quality of cooperation and illustrating the STRATEC-specific terminology and processes, the various phases ranging from “procurement” and “approval for series production” to alteration services are explained in the following.

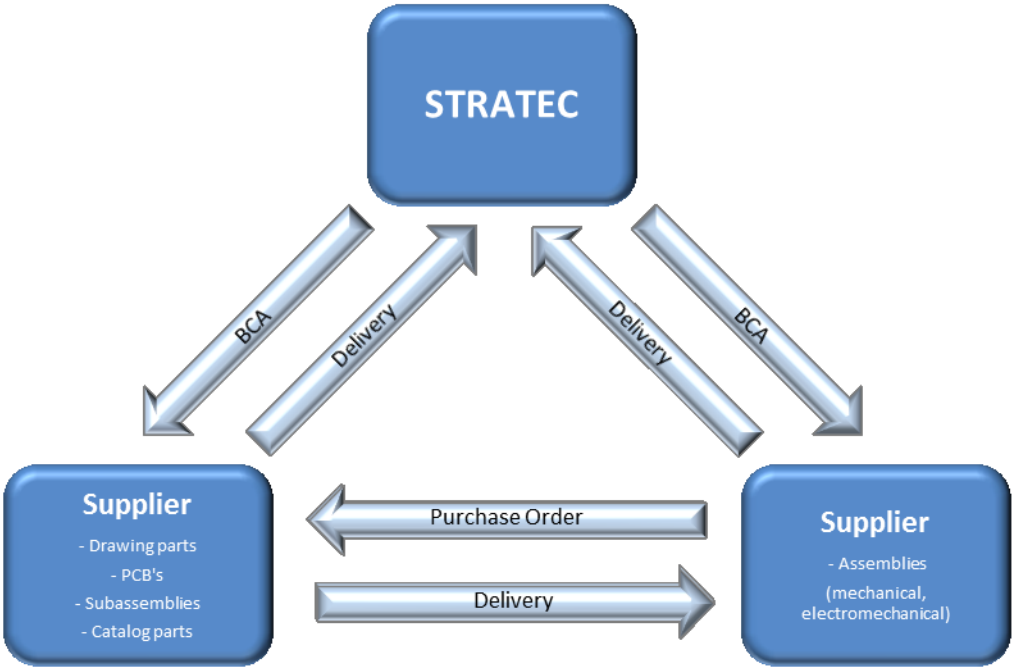
4.1 Objectives

- Increasing performance
- Improving flow of information
- Exploiting the supplier’s potential
- Simplifying procurement processes
- Identifying need for optimization and improvement

4.2 Procurement

Within the procurement process, ensuring the best price, right time, right quantity and right place for the desired product or services is a top priority. For this reason, we explain below in detail the purchasing processes from request, Basic Call Agreement to placing the order including order monitoring. The various documents for inquiries, orders and Basic Call Agreements are created with our ERP system. This ensures that suppliers always receive a unique document number that they must use for further communication with the listed buyer.

In the following graph, the relationship between suppliers, authorized parties and STRATEC is shown.



4.2.1 Inquiry

The inquiry process is started because of a demand of a development project or serial production. The demands of development projects are sample parts or prototype parts. Depending on project progress, pricing scales can be requested in order to process more orders or internal calculations in a simple and cost-neutral fashion.

4.2.1.1 Request for one-time needs/pricing scales

It is important that the conditions defined in the request are found in supplier's respective offer:

- Shipping date
- Product or product specification
- Requested quantity/volume discounts
- Project-specific conditions
- Any additional/non-recurring costs
- Shipping and payment conditions
- Shipping times with references to long-running projects
- Explanations/special features/notes

In case of uncertainties or missing information with regard to the supplied documentation, the supplier must contact the respective buyer immediately.

4.2.1.2 Requesting a Basic Call Agreement (“BCA”)

In addition to a standard request, the following conditions are requested for concluding a BCA agreement:

- Call-off quantities
- Quantities are annual quantities
- Shipping availability (for first batch)
- Reorder level (at least half of the annual amount above)
- Procurement period (for call-offs from BCA after first batch)
- Duration (12 months with option to extend for 6 months)
- Safety stock (at least one call-off quantity or multiples thereof)

These conditions form the basis for a subsequent BCA.

4.2.2 Basic Call Agreement (“BCA”)

The BCA is a so-called volume contract that is concluded based on annual volume, with defined prices, batch size, term, safety stock, reorder level and agreed-upon lead times for the first batch and within the current BCA. Both the supplier and STRATEC commit themselves to these quantities.

4.2.2.1 Term

The beginning of the term is synonymous with the date of the first shipment made by the contractor. The principal is entitled to postpone call-offs from the BCA up to six months into the future if shifting demand among his clients compels him to do so.

4.2.2.2 Batch size

Batch size is calculated considering optimal costs as well as packaging unit and will be agreed upon with supplier. Consequently, at least one batch or multiples thereof can be called off at all times.

4.2.2.3 Reorder level

Once the reorder level has been reached, the supplier is obliged to inform the principal without being requested and without delay. Thus, the process for a new BCA can be set in motion in time to guarantee a secure supply.

4.2.2.4 Safety stock

The contractor guarantees to maintain an agreed safety stock as of the beginning of the contract period. The safety stock consists of at least one batch size or multiples thereof. Shipments from safety stock must be made within three business days to the authorized party. Safety stock needs to be replenished immediately.

4.2.2.5 Authorized sub-suppliers

Third parties and affiliates of STRATEC are entitled to place orders in their own name from the parties' contracted quota as part of a Basic Call Agreement. Placing purchase orders, shipment and payment of the relevant quota will occur strictly between the supplier and the authorized recipient.

4.2.3 Purchase orders

By placing an order, the actual procurement of needed materials and services is set in motion. This is based on agreed-upon unit prices, pricing scales or BCAs. The parameters and guidelines specified therein are to be strictly adhered to. The most important factors are prices, shipment (arrivals), quantities, batch sizes and predetermined specifications.

Note:
The quantities indicated on the purchase order are to be observed. Partial deliveries are only acceptable after prior consultation with and approval by STRATEC.
STRATEC is entitled to order unplanned additional quantities. The supplier is expected to respond flexibly and ensure supplies. This is especially true in the event that shipments have been rejected because of deficient quality.

4.2.3.1 Standard purchase orders

Standard purchase orders are products satisfying one-time demand for pattern or prototype parts in the development phase. Furthermore, indirect materials and services can be handled this way. In exceptional cases, serial products can be ordered with a standard purchase order, but this is the exception rather than the rule.

4.2.3.2 Service part orders

We guarantee our customers a supply of spare parts within 15 working days. This requires an accelerated processing of orders. An order of replacement parts can be distinguished from a standard purchase order by being labeled “spare parts purchase order” on the purchase order form.
With regard to degrees of urgency of spare parts purchase orders, we distinguish between two options:

Option 1 (standard purchase order):

> In this case, we expect the supplier to confirm the purchase order within two working days. This condition will be listed on the purchase order form.

Option 2 (urgent purchase order):

> Here, we expect the supplier to confirm the purchase order within one business day. This condition will also be listed on the purchase order form.

For service parts covering anticipated demand, separate Basic Call Agreements will be concluded so as to ensure a secure short-term supply.

4.2.3.3 Classifications for the Basic Call Agreement

Classifications for BCAs are called call-off orders, which are associated with a corresponding BCA. They are based on the agreed-upon conditions stipulated in the BCA. With each order and corresponding shipment, the cumulative quantity of each BCA is moved up.

4.2.3.4 Tool management

In an effort to optimize costs for our products, we are continually transitioning to tool-based parts. Thus, the importance of tool management is steadily increasing. The tools commissioned by STRATEC generally remain with the supplier. The resulting interfaces and responsibilities are set out in the tool purchase order.

4.2.3.4.1 Tool purchase order (contract)

The tool purchase order is to be clearly distinguished from standard purchase orders by the heading “tool purchase order.” The tool purchase order usually contains a section for the tool or tool change, a section for the first sample test report and a section for the initial sample itself. In this context, the payment terms are defined and divided into the following payments:

- 1/3 after placement of purchase order
- 1/3 after shipment of initial sample
- 1/3 after approval of initial sample

30 days net each

4.2.3.4.2 Purchase of property/loan agreement

After full payment, the tool becomes the property of STRATEC SE. The tool must match the inventory number and must be permanently and unalterably labeled “property of STRATEC SE”. A tool loan agreement between the supplier and STRATEC will be concluded for a period of four years beginning with approval of parts by STRATEC, and which authorizes the supplier to keep the tool in its possession on STRATEC’s behalf. If no one party cancels the contract in writing within six months at the end of the lease, it will automatically be extended for another two years. The tool will be stored properly and free of charge at the supplier’s and will be insured by same for the replacement value. In addition, the supplier shall properly maintain and service the tool regularly at own cost. STRATEC has the exclusive right to use the tool. At any time, STRATEC is entitled to name in writing other purchasers of parts (“parts”) that are or were manufactured using the tool. STRATEC may reclaim the tool at any time by written notice within eight working days.

4.2.3.4.3 Technical documentation

A copy of the tool's technical documentation is to be provided to STRATEC at the time of the initial shipment of the tool-based parts or within five working days after the supplier has created or modified a tool. This documentation includes all technical drawings, parts lists and necessary certificates or other documents (e.g. material certificates, filling studies, etc.) and will ideally be supplied in digitized form using commonly used formats such as *. pdf. *. stp, etc.

4.2.4 Monitoring of purchase orders

4.2.4.1 Order confirmations for purchase orders and BCAs

In order to supply our clients on time, our production must be handled according to the specifications included in our purchase orders. To ensure this handling, purchase orders must be confirmed in writing by the supplier within five working days or two business days (service part orders) after receipt of order. The scheduled dates must be adhered to. The supplier shall ensure that the goods are received on the dates specified by us.

Even with regard to the BCAs, we expect a return of the signed BCA within five business days. The most important point here is shipping capacity, which has been set up in a way so as to ensure an unbroken supply between two BCAs.

4.2.4.1.1 Order confirmation reminder

If the purchase order is not confirmed by the supplier within the specified time limit, reminders will be sent accordingly. The supplier is expected to respond immediately and to create and send the pending order confirmation.

4.2.4.1.2 Reminder for BCA confirmation

The reminder for the BCA is submitted orally to the supplier so as to make certain that the new BCA will be shipped without a hitch.

4.2.5 Shipment reminders

As another instrument to secure production supply, the supplier receives so-called “shipment reminders.” They serve the purpose of reminding the supplier in advance of the upcoming shipment. If it becomes apparent that the scheduled and confirmed appointment cannot be kept, the supplier shall immediately contact STRATEC of its own initiative. This entails drawing up an appropriate plan to maintain production supply through partial deliveries. We expect that all possible measures be taken to safeguard production supply.

4.2.5.1 Shipping warning

If an unexpected event were to arise that prevents shipment from proceeding as previously confirmed, the supplier would receive a shipping warning. This reminder must be processed promptly/immediately and a shipment schedule created (as described under 4.2.5), which has to be coordinated with STRATEC. A continued failure to provide delivery will be followed by legal action.

4.3 Approval for serial production

With this approval, the supplier, as process owner, assumes responsibility for the production and assembly process as well as product quality. In the event of flaws in the production, assembly, testing process or product, the supplier will communicate appropriate measures to STRATEC to avoid or detect deficiencies. Once any necessary approvals by STRATEC have been procured, the measures in question will be implemented.

4.3.1 Requirement for process and product

The supplier must demonstrate the ability to utilize reliable processes to deliver the desired material at the agreed-upon price, right amount, right time and at the right place. The responsibility for implementing all tasks required for this rests with the supplier.

4.3.2 Feasibility

In the context of project cooperation, suppliers analyze drawings created by STRATEC or themselves as well as assembly and test instructions. Through this process, they verify economic and actionable manufacturability, taking into account predefined features, processes, materials and tolerances as well as the resources available to them. This review enables suppliers to provide early detection of potential product and process risks, giving them the opportunity to contribute experiences and suggestions to the mutual benefit of both parties.

As a rule, the following aspects and requirements are to be taken into account for this purpose:

- Can all requirements for readily obtainable parts and/or processes be fulfilled?
- Are the STRATEC requirements for multi-source parts clearly described and are the resulting inspection and quality characteristics likewise identifiable?
- Can process capability be predicted for each test and quality characteristic?
- If multi-source parts are outsourced, the process described in chapter 3.1.8. is to be used

By submitting their bids, suppliers confirm manufacturability, taking into account specifications provided by STRATEC. Possible risks related to reproducible quality will be documented by suppliers in their bids.

4.3.3 Testing equipment

For modules, STRATEC will determine the required tests. The equipment and/or documents referred to in the bill of materials are provided to suppliers free of charge.
Standard measuring equipment such as multimeters, calipers etc. are to be kept by the supplier, who is to perform regular, documented checks on test equipment. In the case of PC-based test equipment, the supplier will generally provide the PC to run the test equipment.

4.3.3.1 Transfer of test equipment

The test equipment shall remain the property of STRATEC. It will be available for use for the duration of the business relationship.
The supplier receives the test equipment as per dispatch note. For the same test equipment, a purchase order is to be recorded detailing that the test equipment is to be returned by the calibration date. If damage occurs on account of improper handling, the resulting repair costs will be billed by STRATEC.
The user interface of the test equipment uses German, but is also available in English.

4.3.3.2 Training in the use of test equipment

For purposes of utilizing testing equipment, STRATEC will provide one-time training. Additional training without changes to test equipment can be provided by STRATEC at cost. Suppliers shall carry out their own additional training within their organizations and document it with appropriate training certificates. It is the suppliers' responsibility to ensure training on the proper handling of test equipment. Training records are to be submitted to STRATEC upon request.

4.3.3.3 Malfunction of test equipment

Each piece of testing equipment has been tested by STRATEC at great expense for proper functionality before being handed over to suppliers. In the event of technical problems of the test equipment during startup or testing, no independent attempts at repair should be made unless they have been approved in writing by STRATEC. The supplier shall discuss such a matter directly with the appropriate STRATEC employee(s) to determine the next steps. Pending a decision by STRATEC, no further tests may be carried out.
For each repair, a separate repair report is to be generated and sent to STRATEC.

4.3.3.4 Calibration

For all test equipment, cyclical calibration is required. The next date on which a calibration has to be made is documented on the type label or serial number label of each piece of test equipment.

The supplier is responsible for compliance with the calibration dates. For this purpose, the supplier reconciles the calibration dates with its production planning. In the event of scheduling conflicts, calibration dates can be moved ahead by agreement or alternative test equipment can be made available.

The return to STRATEC is provided free of charge by the supplier. After successful calibration, the test equipment will be delivered back to the supplier free of charge.

The supplier shall ensure complete return of the test equipment (equipment, accessories and software) in the same packaging it was received in.

In some cases, the calibration will not be performed at STRATEC due to technical reasons, but rather directly on site at the supplier's. This is especially true for scales and other test equipment subject to a high risk of damage or misalignment during transport. During that process, the calibration is done either by STRATEC employees and/or an (external) vendor retained by STRATEC or by employees of the supplier who have been trained by STRATEC. Calibrations performed on site by employees of the supplier must be coordinated with STRATEC's test equipment monitoring office ("PMÜ") before the start.

4.3.3.5 Validation of test equipment

Test equipment is used to ensure and to demonstrate the quality of modules and parts that are manufactured by suppliers. Smooth functioning of this test equipment shall be demonstrated under real environmental and test conditions at the site of the supplier.
For this purpose, test equipment provided by STRATEC shall be assessed through a test equipment evaluation. The evaluation is performed as follows:

Initial validation:
An initial validation is carried out for new test equipment or test equipment that is used for the first time at the respective supplier. Validation is performed on-site at the supplier. Its scope is determined by STRATEC's Systems Integration department. During training in the use of the test equipment, the activities to be undertaken are coordinated with the supplier. The validation documentation shall be submitted to STRATEC for review and approval. Test equipment may not be used again in serial production until it has been approved by STRATEC.

Revalidation:
A revalidation is carried out on site at the supplier, for example, after calibration, repair or technical modification to the test equipment. For this purpose, previously passed samples are tested again (good sample) after successful calibration, repair or modification.
The validation documentation shall be made available to STRATEC for review and approval.
Test equipment cannot be re-used in serial production until it has been approved by STRATEC.

4.3.4 Initial Samples

Initial Samples are products that have been manufactured with standard equipment and under standard production conditions. This includes, for instance, parts that were randomly taken from a production lot. Initial Samples are to be clearly labeled as such.

4.3.4.1 Initial Sample Inspection

With a Initial Sample Inspection (sampling), the supplier documents the required abilities of the product in terms of its quality and condition. This entails checking whether the requirements and characteristics have been met in line with requirements defined in drawings and/or specifications.
Unless otherwise agreed, Initial Sample Inspections in series must typically be carried out for

- new parts
- design, specification or material changes
- use of new or modified tools or spare tools
- changes based on

  - vendor parts
  - subcontractors
  - production methods
  - production processes
  - production sites
  - production and testing equipment
  - manufacturers of parts requiring sample inspection

If the supplier, in turn, plans to implement changes requiring an initial sample inspection, he will immediately inform STRATEC without being prompted to do so.
The supplier will not receive approval for serial production until the Initial Sample Inspection Report has been approved by STRATEC.

4.3.4.2 Initial Sample Inspection Report (“ISIR”)

Documentation of the Initial Sample Inspection is done on a form provided by STRATEC or a supplier’s own template in line with VDA Volume 2.

4.3.4.3 Preliminary approval with conditions (special release)

If, in exceptional cases, initial samples are provided that are not specification-compliant, prior special approval is to be obtained in writing from STRATEC .This special approval only pertains to a certain quantity or time period and includes the obligation to take appropriate measures to get back on track. Each shipment shall be tagged with a special label previously agreed upon and each part must be accompanied by a copy of the special approval.

4.4 Logistical requirements

If there are no predetermined storage and shipping requirements stipulated by STRATEC, the supplier undertakes, taking into account the product specification, to develop and implement the storage and shipping conditions required for quality assurance in accordance with the current state of technology.
If not required by STRATEC, or if no means of transportation has been provided by STRATEC, the supplier will use a transport vehicle appropriate for storage and shipping to safeguard product quality and protect it from damage until the shipment has arrived at its destination.

As a rule, the following aspects and requirements are taken into account for this purpose:

- Generating technical requirements
- Planning of packaging
- Using packaging to protect against damage
- Selecting packaging according to qualitative, economic and environmental criteria
- Preventing possible environmental influences
- Storing according to the FIFO principle
- Complying with product- and material-specific storage conditions
- Warehouse- / storage areas are protected, marked, clearly arranged and clean
- Ensuring unique identification of materials and products
- Proper goods receipt
- Regulations on inventory and disposal responsibilities
- Storage time limits

4.4.1 Packaging (OEM and service parts)

The packaging must be suitable to ensure safe and damage-free transport as well as proper storage. The use of non-commercial or non-recyclable packaging materials must be coordinated between suppliers and technical planners or development planners prior to use. This agreement may be part of a Basic Agreement, or it may be included in the purchase order. If STRATEC requires specific packaging, this will be described in a package statement or in the parts list. Any modification or use of other packaging material may only be carried out after prior approval by STRATEC.

Types of packaging:

- Standard packaging:
  Depending on type and design of the article, packaging is done with commercially available packaging material.

- Packaging according to packing instructions:
  Additional packaging requirements are documented in packing instructions previously issued by STRATEC. The packing instructions are part of the BOM for the respective product.

- Special packaging:
  If special packaging is required for spare parts, it is listed along with the packing instructions in the parts list.
  - For packaging of service parts the packaging from the service parts BOM must be used
  - In the service parts BOM existent original packaging instruction, working instruction or test instruction must be applied
  - If original packaging is mentioned in service part BOM supplier packaging must be used
  - The service part packaging must be completely neutral
  - Only on outer packaging / shipping packaging delivery notes may be attached, only here individual tapes from supplier can be used.

4.4.2 Returnable packaging

Additional packaging (e.g. returnable packaging) will be provided to the supplier in a basic quantity. If this quantity doesn't suffice, for instance, because the supplier wants to use it to store safety stock, costs for the procurement of additional packaging will be divided up after being agreed upon by both sides.
After receipt of the reusable packaging from the carrier, the supplier is responsible for proper storage of empties protected from the weather and damage. To this end, the empties shall be stored in a way that contamination or damage before, during and after the production process can be ruled out.
If dirt or damage occurs during this period, the supplier is required to clean the returnable packaging made available by STRATEC at own cost or to inform STRATEC about the damage. STRATEC handles the repair of damaged empties or will scrap them, if necessary. The cost will be borne by all users of returnable packaging depending on who caused the damage.

4.4.3 Identification and traceability

The supplier shall ensure unambiguous labeling and traceability of its products as well as individual components. Likewise, the supplier ensures traceability of its subcontractors' products. Further details are described by STRATEC in the QAA.

4.4.3.1 Labeling of STRATEC products

4.4.3.1.1 Serialization

A serial number assigned by the supplier must match the structure and specifications provided by STRATEC and may only be assigned once. This avoids duplication between different modules of the same suppliers. This requirement applies to all products supplied by a supplier and to be labeled by a serial number.
There is a special feature for service parts which require serial numbers. Here the serial number of the part (Main part) has to be identical with the serial number of the service part.

Example:	Module (Main part)	12345678	serial number 111111987654321
	Service part	17654321	serial number 111111987654321

4.4.3.1.2 Structure of the serial number

The serial number must be a total of **15 digits.** This labeling consists **of a combination of numbers only**, which means **in numerical form without special characters.** The first five digits represent the STRATEC supplier number; the following ten digits are to be determined by the supplier. As a rule, serial numbers must always be assigned in **ascending and unique** order.
Even if a supplier supplies two different modules that are required to carry serial numbers, each serial number may occur only once.

Example:

WRONG:

CORRECT: module 12345678 serial number 217054711000000
module 23456789 serial number 217054799000001

4.4.3.1.3 Module number (part number)

The module number consists of 8 digits in numerical form without special characters and is predetermined by STRATEC.

4.4.3.1.4 Label material

Specification:

- PVC or polyester white
- Electrical adhesive, non-conductive (> 20 Mohm) (only for PCB)
- Good light and durability
- Temperature range -30 °C to +90 °C
- Resistant to oils, alcohols, humidity, water and weak acids
- Size as ordered

4.4.3.1.5 Label size

The minimum height must not be less than 10 mm. The width is specified by the imprint and product size.

4.4.3.1.6 Service part – Label (shipping label)

- For the service part defined label size is 100x50 mm
- Label of service part packaging must contain the following information → article number, article description, serial number / batch
- The service part label must be applied on the left top on the service part packaging

STRATEC SE – Service Part	
Name	SAMPLE PIPETTOR
Material	10041311 + BARCODE
Lot	00001111
oder	
Serial no.	111112302021482 + BARCODE

4.4.3.1.7 Barcode

Specification:

- Module width: min.0.2
- Barcode height: min. 5 mm
- Empty space/border (white space left/right) min. 4 mm
- Label color: white
- Code: Code 128
- Plain text below the barcode (complete content of the barcode)
- Barcode quality min. type B (ANSI X3.182-1990)

4.4.3.1.8 Arrangement of labels

Barcode labels must always be placed in vertical columns:

4.4.3.1.9 2D barcode

Depending on the version, STRATEC products must be marked with a 2D barcode label. The supplier will be notified about that separately if required.
The applicable requirements are described in the document “General specifications 2D barcode”.

4.4.3.1.10 Number of labels

Unless otherwise agreed, four labels are needed for serial and part number. These shall be affixed as follows:

1. on the actual module
2. on the outer packaging or for printed circuit boards on the ESD packaging
3. on the test report
4. on the shipping note

4.4.3.2 Identification of prototypes

The shipping packaging of prototype parts must be labeled with the inscription “PROTOTYPE”, which must be clearly visible and legible from the outside.

4.4.3.3 Identification on documents for service part deliveries

The delivery note of STRATEC ordered service parts must be marked with “Service Part-Delivery / Service Part-Lieferung”.
STRATEC service part orders will also be marked as “service part orders / Service Part-Bestellung”.

4.4.4 Accompanying documents

If accompanying documents associated with a shipment are missing, the shipment is deemed deficient. This will be indicated to the supplier in the form of a complaint. Accompanying documents are, for instance:

- Delivery notes
- Test reports
- Initial Sample Inspection Reports (ISIRs)

4.4.4.1 Storage of accompanying documents

Accompanying documents are to be included with the shipment in a suitable form and to be stored in a separate package (document cover) if needed. In particular, ESD protection must be ensured for PCBs.

4.5 Repairs

The supplier shall provide a repair procedure for all modules shipped by him as well as for the same modules from possible previous suppliers. This does not constitute a guarantee for modules from previous suppliers. In addition to organizational aspects, the repair process includes both a suitable repair station as well as the necessary resources.

4.5.1 Repair process

4.5.1.1 Shipping to the supplier

Shipping is conducted using packaging suitable for the product, as intended by STRATEC. For return shipments, the supplier arranges for suitable transport packaging, as needed.
The shipment contains a printed delivery note and repair purchase order. At the same time, the supplier will be informed about the shipment by email. In this shipment notice, all parts of shipment are listed along with reason for return. In addition, the form “external repair report” will be attached in Word format for each repair item.

4.5.1.2 Receipt by supplier

If the defective item has not arrived within a week of receiving the email shipment message at the supplier, the supplier is requested to inform STRATEC’s repair department about this.

4.5.1.3 Quote on cost

If a quote is requested for repair, it is to be generated and sent directly to the STRATEC repair department within one week.
The supplier initially estimates the maximum anticipated costs. Billing will be done based on actual services rendered. In addition, an expected return of stock is to be specified, for instance, in the form “Return 5AT after cost approval.” If the estimated cost has been exceeded, STRATEC reserves the right to withdraw its previously granted approval of the cost estimate.
A quote on cost has to be created, even if STRATEC requests a warranty repair that is not conferred by the supplier. In this case, the supplier will have to explain why no warranty is possible from his perspective.
The supplier is required to formulate a joint decision in writing in the form of a cost quote and is to be sent to STRATEC as a response to the email shipping note.

4.5.1.4 Performing repairs and creating a repair report

For each repair, the supplier must complete, sign and send back to STRATEC the original of the form “external repair report” along with the repaired part.
In the field “repair report listing cause and measures executed,” the observed cause of failure is to be described in transparent and comprehensive detail. Similarly, the action plan for the repair is to be explained briefly.
In the chart section of the repair report, all items needed for repair should be listed. The amount, the STRATEC part number (not the supplier’s number!), a short description and a reason why the part has been replaced or has failed should be noted. For PCBs, the part number is to be indicated in the “No.” column (e.g. IC42).
The repair report, including name and date, is to be signed by the person who performed the repair.

4.5.1.5 Performing updates

If the faulty module no longer meets the latest state of technology, an update is to be performed subject to prior consultation with the STRATEC repair department. Unless expressly agreed otherwise, all the parts necessary for updating the module to the status of new production will be replaced.
In addition, a new label with the current item number must be affixed. To this end, the old label must be removed rather than pasted over.
On the repair report, “Update executed” should be checked and a new item number provided below. The serial number cannot be changed, unless expressly agreed otherwise. The material used shall be listed in the table of the repair report.

4.5.1.6 Replacement

A replacement means the replacement delivery of a new module. The old module will be scrapped by the supplier.
An exchange is possible only after prior approval by STRATEC. In this case, “repair replacement” should be checked and the new serial number should be entered. In the interest of clarity, the old serial number must not be retained under any circumstances.

4.5.1.7 Repair completion

It is imperative to mention on the line “repair performed” whether the repair is carried out under warranty, out of courtesy or will be billed. Without this information, STRATEC will not be able to complete the customer repair process and **no billing** will be effected. The above-mentioned processing time for repair doesn’t end until the repaired goods **and** the invoice have been received.

4.5.1.8 Test report

If a test is requested in the item documentation for the repaired module, the full test must be successfully performed after repair. The test report shall be enclosed in the original, including test records of replaced or repaired sub-assemblies.

4.5.1.9 Return delivery to STRATEC

The shipping note provided by the supplier must always include the order number and the return authorization number(s).
The goods receipt posting of repairs is carried out directly by the STRATEC repair department; as a result, a separate shipping note must be created for repairs if they are mixed in with new parts shipments so as to clearly distinguish these repairs from new parts.
The repaired part must be accompanied by a repair report, test report and invoice.
If any of the documents referred to above has not been supplied, the supplier will be dunned as if no delivery had taken place.

4.5.1.10 Billing

When creating an invoice, please note the following:

- Invoices for repairs may not be bundled with new parts
- The repair authorization number must be specified on the invoice
- The repair costs must be listed separately for each repair
- Invoices for warranty repairs will not be accepted
- For warranty repairs that are rejected by the supplier, an estimate must be sent to the STRATEC repair department in advance

4.5.1.11 Repair turnaround times

The supplier undertakes to make repairs within a lead time of **15 working days** from dispatch at STRATEC to return at STRATEC. Lead time ends after the full receipt of part, repair report and invoice.

4.5.1.12 Deadline monitoring

In tandem with the procurement of new parts, the supplier will be dunned weekly regarding missing information and exceeded deadlines.

4.5.1.13 Responsibilities

All inquiries, appointment notifications, deliveries, invoices and reports concerning repairs are to be directed to the STRATEC repair department.

4.6 Changes to parts and modules

Changes to parts and assemblies are subject to the STRATEC change service management and are coordinated by the same. The nature, scope and the implementation of changes are communicated to the supplier using change notifications.

5 Quality Management

5.1 Quality Management System

The supplier who supplies products to STRATEC, undertakes to install a Quality Management System (“QMS” or “Quality Management System”) in accordance with the requirements under DIN EN ISO 9001 and/or DIN EN ISO 13485 in their current version or an equivalent quality management system that at least meets all substantive requirements under DIN EN ISO 9001 and/or DIN EN ISO 13485.
Further details are described in the STRATEC quality assurance agreement (QAA).

5.2 Quality Assurance Agreement (“QAA”)

The QAA is a document that is applicable alongside this Supplier Handbook.
It applies to suppliers who conclude or have concluded supply agreements with STRATEC and describes the quality assurance measures that are required within the supplier’s quality management system.
This agreement also applies to the supply relationship between the supplier and STRATEC-affiliated companies as defined under Section 15 et seqq., AktG.
The supplier commits its subcontractors to comply with the same obligations it assumes under this agreement. STRATEC may request documented evidence from the supplier that the supplier is satisfied as to the effectiveness of its subcontractors’ quality management systems. Likewise, STRATEC may expect that the supplier provides written verification and other items evidencing quality compliance from its subcontractors.

5.2.1 Warranty

Both STRATEC as well as each authorized party is entitled to make warranty claims and launch investigations into defects on its own behalf. If defects occur within the statutory warranty period as of the time goods are received by STRATEC and/or its authorized parties, any rework, replacements, removal of consequential damage and/or repair costs and consequential costs are borne by the supplier. This does not include complaints whereby the supplier can demonstrate that they have been caused through gross negligence on the part of STRATEC and/or its authorized parties.
The limitation period shall be 24 months from the time STRATEC and/or its authorized parties receive the goods.

5.2.2 Expense allowance

In cases that give rise to additional expenditure on the part of STRATEC on account of non-fulfillment of the requirements stipulated in the Quality Assurance Agreement (QAA) or in the Supplier Handbook, STRATEC will charge compensation − regardless of the material damage declared in a complaint − according to the actual expenses incurred by STRATEC or €500, whichever sum is lower.

6 Communication

In a business relationship, the correct addressing information, a targeted flow of information as well as direct and short communication channels are of considerable importance. The supplier and STRATEC will create a joint communication matrix for this purpose.

6.1 Communication matrix

The communication matrix is defined and distributed jointly within the respective business relationship. Contact persons and managers of the respective functional areas are listed. In addition to aiding the regular flow of business activities, this matrix is also utilized for complaint and escalation management.

7 Applicable documents

- Basic Agreement
- Code of Conduct (CoC)
- Confidentiality Agreement
- General Conditions of Purchase
- General Specifications 2D barcode
- Quality Assurance Agreement (QAA)