Handbook for Suppliers

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1 General Information

1.1 Purpose, Background and Objective of this Handbook

1.1.1 Background to this Handbook

The requirements our suppliers have to satisfy are taken for the most part from the newest versions of DIN EN ISO 13485, DIN EN ISO 9001 and EC Directive 93/42 EEC.

This handbook does not replace the requirements of the above-mentioned standards; it defines the requirements specific to Löwenstein with regard to the standards mentioned and give help to understand the Löwenstein strategies.

1.1.2 Löwenstein Mission and General Principle

Mission Statement

We have committed ourselves to diagnostic, therapeutic technologies in medicine. We focus our activities on the needs of the patients, medical personnel and our partners, whom we provide with system solutions of innovative products and services. We are confident of our experience, inventiveness and motivation in developing further innovations and generating standards of the best quality for demanding markets around the world.

We promote a company culture with four central values:

- Personal responsibility
- Enthusiasm
- Creativity
- Achievement

In this atmosphere we continually renew ourselves and collectively press ahead with change.

1.1.3 Löwenstein Vision

We see ourselves as a developing management company with outstanding access to markets for which we seek national and international suppliers. Continuous, sustainable growth of Löwenstein is contingent upon concentration on our core competency. For support in other areas we need to enter into strategic partnerships. This step requires the examination of long-held beliefs about customer and supplier relationships.
We take care of only final assembly and final tests conducted in-house. Therefore, Löwenstein needs the right partners in order to be able to pursue the vision, which requires

- continuous improvement of our production and supplier network
- with competitive and reliable supplier structures based on a
- highly developed logistics supply chain.

Our vision contains the following four core elements from which critical requirements can be derived:

A living, breathing network ➔ Great flexibility

Added value and supplier network ➔ The best partner in the entire network

WM assembly and production system ➔ Unlimited efficiency

Optimum material supply system ➔ Everything always on hand

Löwenstein would like to win over its strategic suppliers for this vision.

1.1.4 Objective of this Handbook

Löwenstein delivers on time high-quality medical devices which satisfy customer requirements. In terms of the vision elements described in 1.2, we require the same of our suppliers. This document is intended to communicate the demands made by Löwenstein of its suppliers, particularly with regard to quality management, organization, service and communication.

The supplier handbook serves as a manual for highly effective cooperation between suppliers and Löwenstein.

1.1.5 Purpose of this Handbook

The quality of our partners in matters of competence, flexibility and reliability and the interplay throughout the supply chain determine customer satisfaction and the competitiveness of our company.

In order to respond appropriately in the future to the continuously developing quality and flexibility requirements of our customers, we need capable partners who commit themselves to more than the basic requirements and who want to face the challenges of the future together with us. This is one of the reasons why Löwenstein strives to integrate its partners in Löwenstein processes at an early stage.

In addition to other systems and activities, this supplier handbook and its implementation should help to ensure both the timely delivery of error-free products purchased by us and the competitiveness of our added value network.

Löwenstein pursues a high-quality and lasting partnership with its suppliers. This handbook should help to improve the relationship between Löwenstein and each of its partners and to avoid misunderstandings.

1.2 Area of Application for this Handbook

This handbook applies to suppliers of production goods (including trade goods) and services of Löwenstein, irrespective of the suppliers' location. The requirements apply also to companies which belong to the Löwenstein group and/or which deliver to other Löwenstein locations.

1.3 General Requirements Made of Our Suppliers

1.3.1 General Requirements

Our purchasing strategy is based on our previously defined economic requirements. It is understood that we and our partners both focus on the long-term joint economic

advantage of our partnership. Our objective is to satisfy the ever-increasing technological quality requirements of our customers despite declining market prices resulting from limited resources for health care.

We build on cooperation and shared responsibility for continuous improvement of processes according the ISO 13485. Therefore we prefer to do business with suppliers whose corporate philosophy is similar to our own.

Our business ethics are based on openness, trust, predictability and reliability for products which bear the Löwenstein name. The business with the many customized parts based on technical drawings does not always run smoothly from the start. Cooperation is therefore impossible with a supplier who cannot identify with our quality demands. We can ensure the best possible development of our components when we have long-term partnerships with companies specialized in providing parts as per drawings. This way of working allows us to guarantee efficient low-waste processing – with the best prices for our customers.

Together with our partners we strive for top-level quality and efficiency. Our suppliers should fulfill the following requirements:

- established and practiced quality management system, preferably based on DIN EN ISO 13485 or its equivalent
- delivery dependability and contract fulfillment
- highly adaptable in response to ever-changing market requirements
- competitive prices, appropriate to the market
- great flexibility to cope with fluctuating needs
- propensity for innovation
- active involvement in working out economical and feasible production solutions
- willingness to continuously examine and optimize the quality of communication and logistical cooperation
- willingness to sign confidentiality agreements with Löwenstein

1.3.2 Observance of Legal Regulations and Product Safety Measures

Our suppliers agree to familiarize themselves with all the legal rules and regulations and standards relevant to product safety of the supplied product in general and for delivery to Löwenstein. The applicable legal regulations and relevant standards (VDA, DIN, etc.) are the minimum requirements when no express reference is made in individual cases. In case of doubt, the generally accepted state of science and technology apply.

Löwenstein is to be informed immediately when a nonconformity is detected in the product function which could pose a hazard to life and limb or which could increase the risk of property damage. In such cases Löwenstein supports the use of a cause analysis where possible and reasonable. Corrective measures will be determined according to objectively defined needs.

1.3.3 Requirements for Customs and Export Regulations

In its role as an Approved Economic Operator (AEO), Löwenstein must comply with official requirements, some of which also apply to our suppliers.

Long-term Supplier Declaration

If the need arises, we will require that you provide us with a Long-term Supplier Declaration as per ECC. We will prepare the relevant form and send it to you. You are obliged to check it, add to it, or to correct it if necessary.

Certificate of Origin

If the conditions for a Long-term Supplier Declaration are not fulfilled, we require a Certificate of Origin from you. In this case you have to request the appropriate certificate from your chamber of commerce and forward it to us.

1.3.4 Product Liability

During the life of the business relationship, the supplier is required to maintain product liability insurance which, among other things, covers claims for damages related to recall actions or other measures taken in the market. Upon demand, the supplier is required to present the insurance policy to Löwenstein. The Standard Conditions of Purchase apply here.

1.3.5 Emergency Management

Suppliers are required to create emergency plans in order to ensure ability to deliver in an emergency. Events (strikes, fire, or bankruptcy of sub-contractors) which can negatively affect ordered deliveries with regard to product quality, delivery dates or quantities, are to be reported to Supply Chain Management at Löwenstein as soon as they become known. The supplier must make appropriate provisions so that he will be able to delivery error-free products in the quantities ordered despite such emergencies. Upon demand by Löwenstein, such arrangements are to be incorporated in an emergency plan and implemented.

Examples of possible provisions are:

- establish minimum inventory level
- maintain / qualify alternative production possibilities
- find alternative sources of supply for semi-finished goods
- set up sufficient IT security measures
- secure flexible capacity in order to ensure ability to delivery with short-term finishing work (weekend word, extra shifts, etc.)
- set up communication matrix with contacts and representatives in separate departments
- etc.

1.3.6 Health and Safety

Suppliers ensure that resources, equipment and supplies are assessed in accordance with health and safety regulations, are professionally handled and can therefore be safely used throughout their periods of use. Possible sources of hazard are

to be noted, assessed and examined for potential improvement. Employees are to be regularly trained in health and safety measures.

Country-specific legal regulations are to be observed. Child- or compulsory labor as specified in German jurisprudence is strictly prohibited internationally in the production of goods delivered to Löwenstein!

1.3.7 Environment

We expect that our suppliers handle raw materials, products, packaging and waste in an environmentally conscious and proper manner. All finished products, semi-finished products, raw materials and packaging must comply with German legal requirements and European directives. Further requirements are specified separately. Furthermore Löwenstein expected a sustainable handling with all available resources.

1.3.8 Standard Conditions of Purchase

The Standard Conditions of Purchase are valid for orders/deliveries and are binding, also in addition to any other signed contracts.

The current version of the above-mentioned conditions can be downloaded from our Internet site at:
Standard Conditions of Purchase Löwenstein Medical Technology

1.3.9 Supplier Application

If you would like to receive current requests for proposals, please fill out the "Supplier Application" on our Internet site. If a need arises, we will send you our request.

1.3.10 Confidentiality

Löwenstein and its suppliers agree to use all documents and knowledge which they receive in connection with their business relationship only for the purposes of the business relationship and to keep said documents and knowledge secret from third parties with the same degree of care as with their own documents and knowledge. Confidentiality is maintained even after termination of the business relationship. This obligation applies to employees, sub-contractors and service providers. The parties will enter into a confidentiality agreement for the regulation of further details.

1.3.11 Gifts

We consider highly ethical principles as the basis of our trustworthy and cooperative business relationship. Our employees are therefore not permitted to accept gifts, free services, allowance in money or anything comparable. We ask that you delete such positions from your quotations.

2 Strategic Cooperation

2.1 Supplier Selection Process and Selection Criteria

2.1.1 Early Involvement in Development Process

Before the decision is made to purchase a certain product, Löwenstein is required to investigate alternative acquisition options. This should be done during the development phase for new products. Strategic Purchasing at Löwenstein works closely with Research & Development and Quality Management and with preferred strategic suppliers. The objective is to find innovative and economical solutions which are jointly developed in advance of final technical specifications.

2.1.2 Inquiries

Procedures

Before Löwenstein enters into a planned business relationship, our Strategic Purchaser decides whether a confidentiality agreement should be signed with a potential supplier in order to protect our know-how.

Inquiries are sent to several potential suppliers, depending on the article (value) and market situation. A potential supplier receives the inquiry along with the Sample Trial Outline (see next section), the Manufacturing Feasibility Study form and information about data which the supplier's offer should include. The supplier's offer must take into account all general conditions (lot size, terms and conditions for delivery and payment) and technical specifications. As a rule, a technical meeting is held with the potential supplier and representatives from Strategic Purchasing, Research & Development and Quality Management.

On a related note, we expect our partners to critically assess our technical solutions and to bring creativity and direct responsibility to the process, from which suggestions for improvement or optimization could emerge.

Finally, Strategic Purchasing compares all offers received and selects the supplier who fulfills the requirements and offers a reasonable price along with ideal logistics.

Sample Trial Outline

This defines the scope of a successful sample trial and lists all required documents to be attached to the initial samples.

Manufacturing Feasibility Study

The offering party (potential supplier) uses this form to assess and confirm manufacturing feasibility. Space is provided for entry of proposed modifications which could be beneficial from a manufacturing perspective or maybe which parts of the specifications are missing for a clear description of the article. This form should prompt a dialog between Löwenstein development and the offering party with the goal of producing articles at optimal cost and technical possibilities.

E-Numbers

Documents generated in the development phase of a project are to be labeled with an "E" in front of the article number (e.g., E-1548). Such kinds of documents are only base for technical discussions. It is not allowed to deliver initial samples or serial production based on “E” drawings!

2.1.3 Selection of Suppliers (Supplier Qualification)

For suppliers who have not yet been approved, qualification is made by Strategic Purchasing and Supplier Quality Assurance on the basis of following assessment criteria:

History

If a supplier has a history of satisfactory deliveries of other products with a comparable degree of manufacturing difficulty (quality level) the supplier can be approved. Approval of an initial sample and valid purchase orders are required before the supplier can make regular deliveries.

On-site Review

An employee from Löwenstein conducts a product- process- or system audit at the supplier's site. Approval of the initial sample and valid purchase orders also are required before the supplier may make regular deliveries.

Quality Assurance Agreement

An appropriate QAA must be concluded with each new supplier. The contents are inspired by the usual methods, procedures and regulations and are intended to be authentic to union organization normative, regulatory and special points. The design of the QAA is done in direct consultation of the partners on the basis of the Löwenstein template.

2.1.4 Contracts (Blanket Contracts)

Löwenstein enters into contracts (blanket contracts as installment (delivery) contracts) with suppliers for all A-parts (important product function, need-based high-quality part) and for all parts considered critical to the market. Strategic Purchasing is responsible for new contracts and their confirmation by supplier.

2.1.5 Service Level Agreement (SLA)

Löwenstein strives for active and open cooperation with selected suppliers. The areas of cooperation include forecasting and ordering and delivery processes.

The general conditions for this logistical cooperation are set down in a Service Level Agreement (SLA). To help make this part of the cooperation run smoothly, Löwenstein provides the supplier with access to the Internet-based supplier portal.

2.2 Supplier Development Program

To develop and for care of strategic partnerships it is necessary to invest in special efforts. To achieve this goal Löwenstein offer a supplier development program or request the participation of it.

2.2.1 Goals of our Development Program

- To make technological know-how usable for Löwenstein
  - To find the right strategic partners for the future
- System and process development on the part of the supplier
- Cost optimization
- Improvements in quality, reliability and effectiveness of cooperation between Löwenstein and its suppliers

2.2.2 Benefits for Suppliers

- Support from Löwenstein with supplier's business development leads to internal and external cost savings
- long-term customer-supplier relationship with Löwenstein is established or strengthened (planning certainty and cost stability)
- Influence on internal Löwenstein processes: the partnership is not a one-way street
- Improvements benefit supplier's other customers too

2.2.3 Condition: Openness-Honesty-Commitment

We see the partnership program as an opportunity to optimize our processes. An open and honest exchange is absolutely necessary for this purpose. Amongst other things we mean by it e.g.

- Specifications without any doubts
- Letter of Intents (LOI)
- Long term agreements/contracts
- Escalation models in case of problems
- and much more

2.3 Supplier Assessment

2.3.1 Supplier Assessment with focus on Quality

General

The Löwenstein supplier assessment registered all performed incoming inspections according the special rating criteria. The quality delivery performance of all suppliers are visible at any time in our ERP system “ABAS”.
Furthermore we evaluate on regular base the quality situation of all delivered goods within our assembling department and out of the returned goods from our customers.
The overall rating under quality perspective will be presented as a school grade from “1” as maximum possible to “5” as lowest ever. Our target for a good supplier is at least the grade of “2”.

This rating will be taken under consideration in case of new contract awards. In case of permanent low performance the assessment guides to individual activities.

The Löwenstein supplier assessment will evaluate once a year and sent to our suppliers on individual demand starting at February for the past calendar year.

Assessment

The quality assessment of each supplier contains:

- The quantity of all NOK parts in relation to all delivered parts in ppm (parts per million). The target level is </= 200ppm/year, more than 2.000ppm/year are not acceptable
- A factor which displays the severity of each failure. A fault recognized first by our customer has a higher severity than a failure which was detected during our incoming inspection. Additionally it will be considered whether a failure occurred the first time or if it is a repeatable fault after implementation of corrective actions.
- The total amount of non-conformity reports (NCR) in relation to the total amount of incoming delivery positions each calendar year.
- A soft fact which consider the collaboration in case of concerns. For this soft fact the reaction speed, the active root cause analysis, the pro-active communication toward Löwenstein and the reliability of corrective actions are important.

2.3.2 Assessment of Delivery Quality

Comments on Delivery Reliability and Adherence to Quantity Requirements

The measurement of punctual delivery (delivery reliability) tells Löwenstein whether the supplier has delivered goods as agreed. A check is also made of the delivered quantity against ordered quantity.

A supplier's delivery reliability and adherence to quantity requirements can be called up in our ERP system at any time. In the event of a poor assessment or upon request by a supplier, Löwenstein can provide an individualized EXCEL-based analysis and discuss same with supplier.

Data Capture and Assessment of Delivery Reliability and Adherence to Quantity Requirements

Based on order data, the ERP system determines the contractually agreed delivery date or a specially requested date (in exceptional cases, such as unplanned customer order, the requested date may come before the agreed date) and, after delivery, the system obtains the actual delivery date from the goods posting entry.
Accordingly, the system reports variances in the dates.
It also compares the ordered quantity and delivered quantity, and likewise assesses and grades the supplier's performance.

Assessment of Delivery Reliability:

Late: < two days = 1, < four days = 2, < 10 = 3, < 15 = 4, from 15 = 5
Early: < two days = 1, < five days = 2, < 8 = 3, < 10 = 4, from 10 = 5

Assessment of Adherence to Quantity Requirements:

Variance <=1% = Note 1; >1% and <= 10% = 2; >10% and <= 40% = 3;
> 40% and <= 66% = 4; > 66% = 5

2.4 Supplier Assessment by Audit

2.4.1 Purpose and Contents

We examine our suppliers for their suitability to deliver products. When the assessment is positive, the supplier can be added to or retained in the list of "approved suppliers".

The external audit consists of a visit to the supplier's site and subsequent supplier assessment. A system-, product- or process audit may be conducted.
A system audit assesses the effectiveness of the QM system.
The product- or process audit assesses the effectiveness of relevant QM issues on the basis of the product or the process.

For all audits a report will created which contains all findings and potential improvements. Löwenstein require in case of findings an individual statement or action plan from the supplier.

2.4.2 Need for Supplier Assessment

The following reasons could prompt a supplier assessment (external audit):

- Addition of a supplier in the list "approved suppliers"
- Complaints about products
- Exceeding allowed quality key performance indicators in supplier assessment
- Clarification of technical problems
- Complaints about environmental protection requirements

Our guideline stipulates that all suppliers who deliver A-parts are subject to a supplier assessment.

2.5 Ensuring Supply Chain and Ability to Deliver

2.5.1 Supplier's Direct Responsibility

Direct responsibility for ensuring delivery of raw materials or purchased parts.

One of Löwenstein's most important objectives is 100% ability to deliver. Achieving this goal gives us a decisive advantage over our competition. Löwenstein suppliers are obliged to take all required measures in order to guarantee their own ability to

deliver. Löwenstein expects its suppliers to place highest priority on their ability to deliver.

The supplier's securing of his own supply chain is absolutely necessary. Delivery delays due to a sub-supplier's inability to deliver will not be accepted. The following are particularly important in this regard:

- buffer inventory (supplier's own or sub-supplier's)
- minimum inventory levels (of finished goods, raw materials and purchased parts)
- emergency plans (in the event of insolvency or fire, for example)
- general contracts, blanket orders
- lot sizes and delivery time optimization
- ownership of tools and tool management
- second source
- systematic screening of suppliers at risk

The structured organization used to safeguard the supply chain is closely examined during an audit.

2.5.2 Purchased Parts Specified by Löwenstein

Löwenstein stipulates the source of supply for some purchased parts. In these cases the responsibility for safeguarding the ability to deliver is completely in the hands of the supplier who acquires these purchased parts for components the supplier delivers to Löwenstein, too.

2.6 Continuous Improvement Process (CIP)

2.6.1 Significance for Löwenstein

Löwenstein expects its suppliers to work actively on improving processes and products. The goal is to achieve continuous optimization of the entire system, not just internal supplier matters.

An all-encompassing philosophy of continuous improvement must be evident throughout the entire supplier organization. Suppliers should make every effort to make continuous improvements in quality, deliveries, services, deadlines and prices.

Because we pursue the goal of improving the whole system, a Continuous Improvement Process is required along the entire supply chain. Efforts may involve raw materials, purchased parts and subcontractors but may also include processes between supplier and Löwenstein and issues internal to Löwenstein.

Remark:
In case of any influence of improvements to released raw materials, characteristics of articles, manufacturing processes or involvement of sub-suppliers, direct or at sub-suppliers site, the changes has to be announced to Löwenstein or if applicable

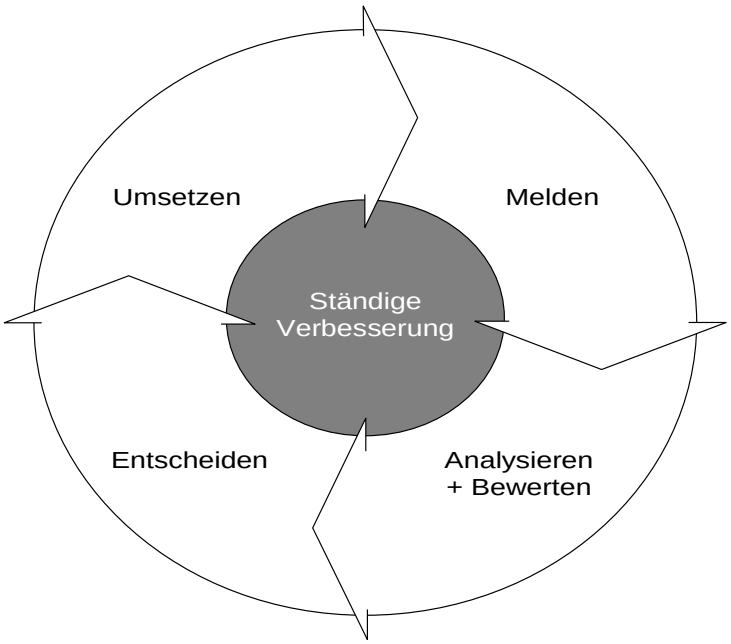
also to be released by Löwenstein. Both have to be done before implementation! (see also chapter 3.5.3, 4.3.8)

2.6.2 Structure

Appropriate structures and organizational schemes should be in place so that a Continuous Improvement Process can be practiced. Potential improvements should be systematically noted, analyzed and implemented. Implementation efforts should be monitored with an appropriate system (suggestion program, CIP meetings, CIP boards, Poka Yoke, Kaizen. . .). Suppliers should be able to demonstrate their CIP practices with documentation and completed projects.
Examples of measurements:

- unplanned machine downtime
- machine settings, change of tools and machine changeover time
- cycle time
- waste, rejects, rework and repairs
- insufficient use of factory premises
- variation in results (repeat accuracy)
- failures due to production adjustments or conversions
- unnecessary handling and warehousing
- low capability in Measurement System Analysis (MSA)
- lack of customer satisfaction, e.g., complaints, repairs, returns, incorrect deliveries, incomplete orders, warranty claims, etc.
- purchasing projects (cost or logistics optimization)
- and so on

2.6.3 CIP as Permanent Feedback Loop



3 Operational Cooperation

3.1 Order Processing

3.1.1 Scheduling

Our Service Center (Operational Purchaser) is responsible for the scheduling of all our qualified purchased parts. Our ERP system automatically generates order proposals on the basis of defined scheduling parameters (see below), specified planned needs and existing customer orders. Employees in the Service Center check and approve the order proposals and forward them to our suppliers.

3.1.2 Order Proposals

Each week Löwenstein generates in the ERP system a forecast of production needs for the next 15 weeks. The resulting total needs for individual parts can be called up (as order proposals and forecast information) in our supplier portal. The supplier uses the information to coordinate coverage of his needs with his own suppliers. The order proposals are based on the information currently available (lot sizes, procurement time, inventories), present needs from actual customer orders and planned purchases. Interim changes to master data and consumption which varies from plan (+ or -) have an effect on deadlines and quantities in order proposals.

Our system is subject to continuous optimization intended to increase inventory reliability. We systematically eliminate any potential causes of error. For example, if an incorrect posting leads to an unusual order proposal outside the standard framework, Löwenstein will check this together with the supplier in order to prevent erroneous scheduling.

3.1.3 Scheduling Parameters as Critical Factor in Support of our Vision

Scheduling parameters per article (minimum inventory level, lot size, procurement time) are regularly examined as part of order proposal assessments by our Operational Purchasing team.

When general conditions change, adjustments are made to scheduling parameters in conjunction with Sales, Production Management, Strategic Purchasing and the supplier.

Because great flexibility and correspondingly short delivery times make up one of our most important objectives, we need suppliers who give us their support and enable us to set up the necessary scheduling parameters.

Löwenstein does not want to make agreements with suppliers for any delivery times of > five days. Corresponding logistics models (e.g., Kanban inventory at our supplier's site) are mutually agreed to and jointly set up. Lot sizes should also be flexibly defined and based on packaging units. Changes made by the supplier which can have an effect on lot size or procurement time are to be reported immediately to Supply Chain Management at Löwenstein.

3.1.4 Order / Partial Deliveries from Contracts

When a Löwenstein-specific or supplier-specific part is required for which a technical drawing has been created, the currently valid technical documentation will be submitted before the initial order for the part are placed.

When changes are made, Strategic Purchasing sends the new technical documentation to the supplier to ensure that the technical documentation is maintained and updated by the supplier, irrespective of any future needs. The current drawing index is included in the order text. It is the responsibility of the supplier to compare the index from the order text with the supplier's own production documentation for every order. Löwenstein is to be informed immediately if the two pieces of documentation do not have the same status.

If a standard part or a supplier's standardized article is required for which there is no technical drawing, the order text contains the standard part designation or the supplier's article number and the reference article number from Löwenstein. The order is placed without accompanying technical documentation since the documentation is on file with the respective standards institution.

Orders are made primarily per e-mail, but can also be faxed and stored electronically. Orders are placed without original signatures, but are nevertheless considered binding.

Löwenstein expects every order to be confirmed by supplier. Any separate arrangements which differ from these are allowed only in the form of written contractual agreements. The Service Center (Operational Purchaser) checks the incoming order confirmation and compares it with the order. Suppliers will be informed of any missing order confirmations once per week in order to rule out any transmission errors.

3.1.5 Ordered Quantity

The ordered quantity is based on the ABC quality rating, packing unit or agreed lot size and, where applicable, a minimum purchase quantity. The categories are defined in the following paragraphs:

- A-X parts are ordered as frequently as possible; at least twice per month. Given the parts' good forecast probability, use can be made of efficient VMi (Vendor Management Inventory) procedures via our portal or Box-Kanban procedures. In this case optimization is appropriate for low stock levels and is necessary for a reduction in capital commitment.
- A-YZ parts are ordered as frequently as possible; at least once per month. Where it makes sense logistically, Kanban procedures are used with forecasting.
- B-parts are ordered four to five times per year.
- C-X parts are ordered to cover the needs of one complete year.

During the launch phase of a new product, information gained from the market can lead to variances and fluctuation in needs. Any changes are agreed to in close cooperation between supplier and Operational Purchaser.

3.1.6 Unplanned Additional Quantities (Tender)

If we have large customer orders (e.g., from the tender business) which cannot be covered with deliveries based on current sales plans, steps must be taken to prevent errors in materials planning. Our Service Center (specifically, the production scheduler and Operational Purchaser) works closely with the supplier involved, Sales department and Production department.

Measures (e.g., buffer inventory) for coverage of such peaks in needs are agreed to during contract and price negotiations between the responsible Strategic Purchaser and the supplier.

3.1.7 Order Number

Every order received on the telephone or in writing is given an order number. The order number is to be clearly marked on all related documents (e.g., order confirmation, delivery note, etc.).

3.1.8 Delivery Date Monitoring

Our scheduling system functions without backlogs. In our ERP system we use real-time forward and backward scheduling with dynamic needs coverage assignments based on promised customer deliveries. By analyzing the critical path, we are able to identify potential bottlenecks early and avoid them. With the help of a needs coverage analysis, the Service Center (Operational Purchasers) receives early warning of an article that is being consumed more quickly than originally planned. An earlier delivery, to be made ahead of current orders, can then be arranged with the supplier.

If the Service Center realizes that previously ordered items could be delivered too early, an agreement can be made (with significant interest disadvantages) with the supplier to postpone delivery.

For purposes of calculating discounts, the delivery date for goods received too early is the actually agreed date and not the date on which delivery is made.

3.1.9 Incoming Goods and Complaints

Upon delivery of goods, Löwenstein employees check whether the correct amount and type of product has been delivered, whether the delivery has any obvious damage or outwardly recognizable defects, whether all required documents (delivery note, etc.) are attached and whether the products and their packaging are correctly labeled.

Löwenstein informs the supplier of any nonconformity. If a defect or nonconformity is discovered at a later time, the information is likewise to be forwarded by Löwenstein to the supplier.

If Löwenstein has a complaint about a delivery, a letter is sent to the supplier along with a complaint report and a debit note so that settlement (value equalization) can be made immediately. The debit note with return delivery of the goods covers the purchase price of the underlying order and the cost of return delivery. If it is necessary and possible to sort or rework defective units to meet production demands, an agreement for such action is made with the supplier, whose account is then correspondingly debited. The guarantee which applies to *not* reworked characteristics

remains unaffected. In doing any sorting and rework, Löwenstein adheres to the economic principle of minimizing damage.

As a rule (depending on the seriousness of the defect and direction from QM), Löwenstein demands a statement in the form of an 8D report from the supplier.

3.2 The Löwenstein Supplier Portal

3.2.1 General

Via the supplier portal Löwenstein lets its suppliers schedule independently, look at the forecast for the next 15 weeks and trigger their own orders.

In the delivery commitment the supplier can see when a need arises for each article. Changes to current orders are possible.

3.2.2 Rights and Obligations

Access to the Löwenstein supplier portal is gained via login.loewensteinmedical.de. With an Internet browser (Microsoft Internet Explorer or Mozilla Firefox) every supplier can log in with access data (supplier number and password) at any time of day or night. Data is synchronized with data from Löwenstein's ERP system about every 20 minutes between 8 a.m. and 8 p.m. Central European Time. Data in the supplier portal are updated with the ERP-captured data and put online. A supplier may log in from 8 p.m. to 8 a.m., but no data update takes place during these hours.

The Operational Purchasers are available during normal working hours or via e-mail for questions and comments from suppliers.

Löwenstein obligations include:

- Via the supplier portal Löwenstein provides the supplier with information relevant to the completion of his work.
- Löwenstein regularly checks the supplier's login and ordering activities and observes the effects on the relevant article inventories. As required, Löwenstein clarifies issues involving the supplier. If necessary, Löwenstein makes agreements with the supplier via the portal regarding joint measures intended to optimize cooperation.

Suppliers' obligations include:

- Löwenstein is to be informed at once if the supplier sees a need to change article master data (particularly the chance to shorten procurement time or other planning-relevant data such as lot size, etc.). Changes in the supplier's own contact data are also to be communicated to Löwenstein without delay.
- The supplier is responsible for providing Internet access to allow use of the supplier portal.

3.2.3 Training

We give a supplier's employees intense training before they are permitted to use our portal. We stand ready to help our suppliers, especially during the start-up phase, with any questions or problems they have in using the portal.

3.2.4 Start-up Phase

The supplier completes a start-up phase before being permitted to generate orders on his own in the portal. During this phase the supplier and Löwenstein work closely together to identify improvement potential, to promote the Continuous Improvement Process and to prevent typical beginner's errors.

3.2.5 Miscellaneous

Expansion stages in supplier portal

Over time the extent of the verification check done by Löwenstein's Operational Purchasers will be reduced so that routine checks can be automated.
Löwenstein will inform the supplier of any changes made to the supplier portal.

3.2.6 Contractual Regulation

Prior to use of our portal as described here, the general conditions are contractually fixed by both parties in a special agreement, which is known as the Service Level Agreement (SLA).

3.3 Logistics Requirements

3.3.1 Labeling Instructions and Accompanying Documents

Every supplier gets a unique order number for each order. The number has to be noted on the accompanying documents. Each delivery must be accompanied by a delivery note with order number and article number. If the number is missing, Löwenstein can refuse to accept delivery and could thereby cause the supplier to miss the delivery deadline. Packaging (outside packaging and individual packages) must also be clearly labeled (at least with article numbers). Labeling of the outside packaging and of the individual packages contained therein must match 100%. The order number and article number should also appear on the invoice.

Samples and prototypes are to be clearly identified as such on the delivery note and packaging units.

Remark:
Löwenstein article number includes at any time the engineering level in alphabetic order.

3.3.2 Packaging

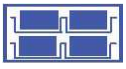
3.3.2.1 Terminology

Article	Parts with the same part number
Inner Packaging	Packaging with direct contact to content goods. Material which is used for saving and/or separation of parts.
Single Packaging	Packaging which contains only one article (parts with same article number)
Outer Packaging	Packaging which contains several individual packages in

	one delivery unit
Transport Packaging	Packaging which enables a safe and simple handling of parts during route transport. Furthermore, it is used for saving parts against outside influences during transport, storing and handling.
Loading Equipment	Equipment for cargo securing, e.g. planks, chains, frames
Handling Aid	Handling Aid is used for heavy and bulky goods which cannot be shipped with normal equipment. It is used for transport and storage. Handling Aids are for example frames of timber or metal, squared timber construction etc.
Strapping	Strapping is used for fixing the cargo during transport and handling, e.g. for cargo securing on pallets.
Transport securing	Equipment for saving the cargo during transport
Stack ability	Several packaging can be piled without damage due to a leveled surface and sufficient stability of packaging.
Overhang	Parts sticking out beyond the top of the pallet
Disposable Packaging	Packaging used for only one delivery
Reusable Packaging	Packaging which can be used for several deliveries
ESD Packaging	Packaging with ESD protection (type C or type S)

3.3.2.2 Explanation of Symbols

Individual Packaging / Inner Packaging

Corrugated cardboard		Shaped inserts/ Shaped interlinings	
Returnable Container		Underliners	
Bags / Protective bags		Intermediate layers, dividers	

Outer Packaging

Corrugated cardboards 	
Returnable Container 	

Transport Packaging 

Outer packaging unit on pallet 	Returnable Container 
Heavy parts on pallet 	Batch 
Pallet cage 	Handling Aid 
Wooden box 	

3.3.2.3 Standard Packaging

Outer Packaging / Loading Unit		
Euro-Pallet	1200 x 800 mm	700 kg
One-Way Pallet	1200 x 800 mm	700 kg
Pallet Cage	1200 x 800 mm	700 kg
Returnable Container	1200 x 800 mm	700 kg
Industry Pallet	1200 x 1200 mm	700 kg
Transport Lock		

Secondary Packaging unit	**Length x width**	**WM-Description**
Schäferbox RK 521	508 x 162 mm	KLT1
Schäferbox RK 421	408 x 162 mm	KLT1
Schäferbox TF 14/7-5	140 x 95 mm	KLT2
Schäferbox TF 14/7-3	300 x 200 mm	KLT2
Schäferbox TF 14/7-2	450 x 300 mm	SK3
Schäferbox EF 4170PP	400 x 300 mm	SK3
Schäferbox EF 4220PP	400 x 300 mm	SK3
Schäferbox LF 531/532	500 x 300/320 mm	SK3/SK2
Schäferbox EF-Series	600 x 400 mm	SK2

Instead of Schäferboxes from Company Schäfer it is possible to use other reusable packaging with the same or smaller dimensions.

Inner Packaging/Individual Packaging/Underliners

Bags
Cardboard boxes
Corrugated cared boards
Shaped interlinings
Underliners
Deviders
ESD protection (type C or type S)

Packaging Aid

Foldaway stacking frame	1200 x 800 mm
respectively	1200 x 1200 mm (Industry Pallet)
Stacking frame	1200 x 800 mm
respectively	1200 x 1200 mm (Industry Pallet)

Stretch film/Shrink film/Foil cover
Strapping with plastic strap / metal strap
Edge protection

Padding material

Paper Plus System
Bubble wrap
Air cushioning pads
Packaging paper
Foam film

3.3.2.4 Heigth Restrictions

Height Restrictions for small parts storage

- 120 mm (KLT1, KLT2, SK3)
- 240 mm (SK3)
- 410 mm (SK2, SK3)

Height restriction for dispatch on Standard Pallets (800x1200)

- EURO1: max. Height: 1500 mm
- EURO2: max. Height: 2000 mm
- EURO5: max. Height: 650 mm

The height of packaging has to be kept as low as possible!

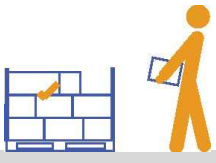
Height restriction for dispatch on Industry Pallets

- EURO3: max. Height: 1600 mm
- EURO6: max. Height: 2000 mm

3.3.2.5 Weight restriction

Packing scheduled for manual handling

Packaging which is scheduled for manual handling should not exceed a weight of



20 Kg.
Packaging exceeding 20 kg has always to be delivered on pallets. The total weight has to be clearly and visibly marked on the top of the box.

Loading units

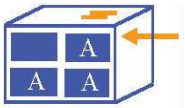
The maximum authorized weight for pallets/pallet cages/wooden boxes/returnable containers is 700 kg. Exceptions require a written permission. The total weight has to be clearly and visibly marked on the top of the box.

3.3.2.6 Labelling

Each individual packaging containing only one article has to be clearly and visibly marked on the top of the box with LÖWENSTEIN-part number and quantity.

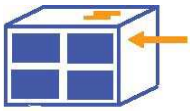
Part number (LÖWENSTEIN)
Quantity

All outer packages containing several individual packaging (each containing the same article) have to be clearly and visibly marked on the top of the box with LÖWENSTEIN-part number, quantity of individual packaging and total weight in kg.



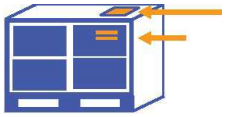
Part number (LÖWENSTEIN)
Quantity of individual packaging
total weight in kg

All outer packages containing several individual packaging (with different articles) have to be clearly and visibly marked on the top of the box with LÖWENSTEIN-Part number, list of part numbers, total weight in kg and “Mixed Shipment”.



„Mixed shipment“
List of part numbers (LÖWENSTEIN)
total weight in kg

Each delivery must include a bill of loading fixed in a waterproof bag on the packaging**.** For more details, please refer to the following page.

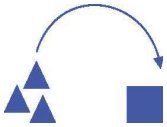


Bill of loading
Complete name and address of sender/supplier
Country of origin
date of shipment
total weight in kg
part number (LÖWENSTEIN)/Quantity
or „Mixed shipment“/List of part numbers (LÖWENSTEIN)

Bill of loading

Contained details	:	Information of Sender / Supplier Information of recipient destination ware house Place, date

delivery date / type of dispatch
Order number/Customer/order date
Total number of packaging
Order code/part number/quantity/destination

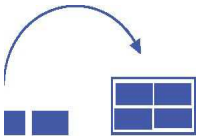


3.3.2.7 Individual Packaging

Individual packaging is e.g. corrugated cardboards, bags, card boards, returnable containers etc. Individual Packaging is the smallest packaging unit. The packaging should contain only one article with the same article number.

Each single packaging has to be clearly and visibly marked with the following details:

- ➲ Quantity
- ➲ LÖWENSTEIN-part number

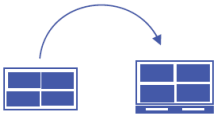


3.3.2.8 Outer packages

Outer Packaging is e.g. corrugated cardboards, returnable containers, etc.. Outer packaging contains several individual packaging. Two types of labelling are possible:

- Transport packaging containing only one article has to be clearly and visibly marked with the following details:
  - ➲ Quantity
  - ➲ LÖWENSTEIN- part number

- Transport packaging containing different articles has to be packed separately and has to be clearly and visibly marked with the following details:
  - ➲ „mixed shipment"
  - ➲ LÖWENSTEIN-part number



3.3.2.9 Transport packaging

Example: Freight on pallets, pallet cages, returnable containers, wooden boxes, parts with oversize, with loading equipment etc. and outer packaging may contain one or several articles. Two types of labelling are possible:

Transport packaging containing only one article has to be clearly and visibly marked with the following details:

- ➲ Quantity
- ➲ LÖWENSTEIN-part number

- Transport packaging, containing several articles, has to be clearly and visibly marked with the following details (marking has to be fixed on an eye-catching place):

- „Mixed shipment"
- LÖWENSTEIN-part number

Changes to packaging have to be discussed with LÖWENSTEIN in advance, as it can have effects on our disposition as well as on our internal logistics.

Remark:
Each packaging of goods which is used by the supplier and not requested explicit by Löwenstein has to ensure a safe transport and that the articles are protected according their individual needs against damages and/or contamination. It is described as “trade usual” in the Löwenstein order text.

3.3.3 Transport Damage

The supplier will be charged for damages incurred by Löwenstein (rework / sorting / additional testing), which can be attributed to inadequate packaging as outlined in Section 3.3.2. If damage to the goods is so extensive that the delivery cannot be accepted, the supplier is at risk of missing the delivery date if he cannot make a timely replacement delivery.

Transport damages are put into two categories. Two different procedures are required, depending on the type of transport damage and type of defect involved.

- obvious transport damage
- hidden transport damage

Determination of Transport Damage

To protect its right to file a claim, Löwenstein must consult with the shipper immediately or within a defined period of time to determine the extent of the damages.

Obvious transport damage:
Obviously visible transport damages are reported immediately to the shipper and are confirmed by the driver's signature on the shipping document.

Hidden transport damage:
Hidden transport damage is reported immediately in writing to the shipper. The deadlines for reporting are e.g.:

- Shipping company: no later than on the sixth day after delivery (§ 60 ADSp.)
- German Railway: within seven (7) days (§ 81/82 EVO)
- Post/DHL: no more than 24 hours after delivery

3.4 Tool Management

3.4.1 Tool Contract

If the manufacture of an article requires special tools, equipment or test equipment, Löwenstein makes special arrangements in a tool contract with suppliers regarding implementation and acceptance of the first regular delivery or of delivery after a

change has been made and of the tool's or equipment's appropriate care and maintenance.

3.4.2 Acquisition of Ownership / Loan for Use Agreement

If the tools, equipment and test equipment (e.g., injection molding tools) also can be used by other suppliers, Löwenstein, for reasons related to supply guarantee, will acquire ownership of the tool or equipment in question and sign a loan for use agreement with the supplier. Moreover, an inventory number is to be placed on the tools, equipment or test equipment and a label affixed to the tool or equipment in such a way that it cannot be lost.

3.4.3 Technical Documentation

As part of the process to obtain approval for regular deliveries, the supplier delivers the "technical documentation" (drawings) for tools and equipment. If the tools and equipment are lost or damaged, the drawings can be used to reproduce them.

3.4.4 Article Discontinuation

If Löwenstein decides to discontinue an article, Strategic Purchasing will demand in writing that the supplier dispose of or return tools, equipment and test equipment.

3.5 Change Management

3.5.1 Change Request

Every change is initiated by a request. Such a request is generally drawn up in co-operation with our suppliers.

Because our suppliers are involved early in the process, orders by sub-suppliers (raw materials) and prefabrications are to be agreed to with our Purchasers from this point on. The aim is to avoid incurring disposal costs or encountering an unnecessary delay in making the change due to a high level of old stock.

3.5.2 Implementation and Project Organization

Once internal Löwenstein approval has been granted, the Strategic Purchaser and the supplier work out a schedule and the scope of documentation required for the change. Amended technical documentation is also provided by Strategic Purchasing. Consideration should be given as to whether old stock is to be used up or scrapped.

For very simple changes the schedule can consist of the deadline for the first delivery.

For complex changes a project plan has to be drawn up which describes the individual steps (e.g., sample delivery by supplier, sample approval by Löwenstein. . .) up to the introduction of regular deliveries and sets down the responsible parties and deadlines.

Löwenstein expects its suppliers to use professional change management, to meet promised deadlines and to be able to report current status of a change at any time. For complex changes both parties should set up joint reports, which are made available to the responsible Strategic Purchaser.

We presume, however, that our suppliers will maintain the agreed schedule and in-

troduce changes in production as planned or will inform us immediately when delays or other problems are detected.

Remark:
Löwenstein take it as granted that serial deliveries after implementation of technical changes are made only after approval of initial samples by Löwenstein.
Alternatively there is the possibility to send the first delivery of changed parts as initial samples for approval. This has to be agreed in advance with the responsible strategic purchaser. The risks of this approach are covered by the polluter pays principle. It will not release the supplier from his own responsibility to ensure that the specification will be fulfilled.

3.5.3 Changes Made by Supplier

The supplier must inform Löwenstein of each of the following changes. Löwenstein then decides if and to what extent a sample trial is required:

- use of another model/design or other material as the one approved for the part.
- use of a new or modified tool (except for consumable tools), castings, molds, models, etc., including additional or replacement tools for serial production
- Series production with available overhauled or rebuilt tools or equipment
- Series production by means of tools and equipment which was transferred in another factory or which comes from another factory
- Change of subcontractors for parts or process-relevant services insofar as they satisfy customer requirements for size, design, function, service life or performance
- Series products, after which tools were inoperative for 12 or more months
- Changes to testing or measuring methods
- Changes to products or processes involving single parts of a series product, which are manufactured internally or by a subcontractor and which affect size, design, function, service life or performance

In the following cases the supplier must request approval prior to the first regular delivery:

- a new part or product (i.e., a specific part, material or color which has not previously been delivered to Löwenstein)
- correction of a defect in a previously presented part
- change of design with impact on drawings, specifications or materials for series products or parts

Situations for which Löwenstein does not require customer notification or a sample trial:

- drawing changes for sub-components which are manufactured internally or by a subcontractor and do not affect the design of the product delivered to Löwenstein (no changes may be made to Löwenstein drawings!)

- relocation of tools at a production site; the tools are used in similar equipment, but no changes to the process are made and no tools are changed or rebuilt.
- changes to equipment but the process and the production methods/technology remain unchanged
- replacement of similar measurement equipment
- job reorganization which does not lead to a change in process flows

Remark:

See also section 4.3.

4 Quality Management

4.1 General QM System Requirements

4.1.1 QM System

Löwenstein shows preference to suppliers that maintain a Quality Management system which complies at a minimum with ISO 9001. Certification as per ISO 13485 may be required for special components. Products delivered to us are to be manufactured and tested according to the regulations of this QM system. Tests which Löwenstein explicitly demands over its specifications are to be observed in addition.

4.1.2 Error Prevention

Error prevention must be given a higher priority over error detection. Adhering to this guideline ought to yield not just continuous improvement in quality but also increased productivity. The state of the art is taken as the benchmark for a reachable quality if not otherwise agreed.

4.1.3 Responsibility for Quality

Our suppliers bear complete responsibility for the quality of their deliveries and services. In particular this means that deliveries of products, components, materials and services correspond fully in every regard to the currently valid regulations noted in the technical documentation accompanying the order. Suppliers are obliged to follow the zero defects philosophy and to optimize their services continuously to that end.

Moreover, we expect from our suppliers that they are in a position to critically regard our technical documentation and to advise us of improvement potential in the manufacturing process. We would like to work out joint solutions that enable us to optimize our technical documentation with regard to production and quality management perspectives.

4.2 Quality Assurance Agreement

Löwenstein enters into a quality assurance agreement with selected suppliers in order to support a long-term, trustworthy partnership. The agreement regulates aspects which are necessary to ensure the required quality of products in addition to our Standard Conditions of Purchase. The Quality Assurance Agreement is agreed to with the supplier and signed by both parties. The agreement should also help to prevent quality problems and to optimize quality costs.
The following issues are treated in the Quality Assurance Agreement:

- Quality management system
- QM in development and planning (sample trials)
- QM in regular deliveries
- Defective deliveries
- Quality management agent

4.3 Quality Assurance prior to Series Production

4.3.1 Project Management – New Development or Adaptation

If a job awarded to a supplier includes product development tasks, the product specifications are to be defined in writing. The supplier is responsible for writing a specifications document.

The supplier is obliged to use a professional project management system in the product planning phase, processes and other interdepartmental tasks. The tool should help the supplier to depict his procedures and describe and schedule activities.

Project plans serve as a means of communication with Löwenstein and as an analytical and steering instrument.

We pursue error prevention and efficiency gains in development, production and assembly processes as the means to maintain our competitiveness. Testing measures, therefore, have to be included in the planning. We demand of ourselves and our suppliers the timely conclusion to projects which satisfy technical specifications.

4.3.2 Check of Technical Documentation

Upon receipt of all technical documentation (e.g., specifications, drawings, parts lists, CAD data) required to support series development, the supplier should check for completeness and consistency in general and for the intended application in particular. Any errors are to be reported to Löwenstein without delay. See also section “4.3.6 Manufacturing Feasibility Study”.

4.3.3 Preventive Quality Planning (APQP)

In the development phase (product and/or process development), the contract partners should use appropriate preventive methods of quality planning, such as manufacturing feasibility study, specification of critical features, fault tree analysis, test plans, test equipment plans, reliability calculation, FMEA, etc.

The supplier should take into consideration experience (process flows, process data, capability studies, etc.) from similar projects and especially from earlier mistakes.
The manufacturing and testing conditions should be agreed to for prototypes and pre-series parts and documented. The goal is to manufacture the prototypes and pre-series parts under conditions as similar to series production as possible.

The supplier is expected to analyze the suitability of the production processes/facilities he utilizes and to document same. If the specified level of capability is not achieved, the supplier has to optimize his rocesses/facilities or conduct appropriate tests of the manufactured products to rule out any defective deliveries. (see also section 4.3.9)

4.3.4 Key Components

In our Key Component Program, we define key components in the development phase. The definitions yield special requirements necessary for advance quality planning and long-term quality assurance. Löwenstein and the supplier involved

jointly agree to requirements (e.g., a special qualification program) and assign the related tasks to Löwenstein and the supplier.

4.3.5 FMEA (Product and Process) (Failure Mode and Effect Analysis)

A systematic approach in the form of a Failure Mode and Effects Analysis (FMEA) may be required in order to analyze potential errors in process development, series start-up and in production, and to plan concrete error prevention measures. The analysis is amended to reflect changes made to a process or specifications.
In addition, FMEA is a method for archiving development results (irrespective of persons involved) and an instrument for continuous improvement. As a living document, the analysis is subject to change throughout the life cycle of the part involved.

4.3.6 Manufacturing Feasibility Study

In conducting a manufacturing feasibility study, the supplier verifies that he has examined and can meet all the requirements contained in current technical documentation. The supplier's confirmation applies to the manufacturing feasibility and verifiability. Moreover, the supplier is required to critically question the technical specifications with regard to their manufacturing suitability. Any suggestions for improvement are to be noted on the form "Manufacturing Feasibility Study".

If a supplier cannot satisfy the technical requirements, this information is also to be provided on the form. The supplier may suggest alternative solutions which would enable him to produce as required or may reject the manufacturability completely.

4.3.7 Test and Control Plans

Löwenstein expects documents such as test plans, production control plan and test instructions for all delivered articles. On request this document hat to be submitted towards Löwenstein.

The test equipment and test methods for the prescribed quality tests are to be specified in the relevant documents. Desired results and tolerances, test scope and frequency are also to be defined along with criteria for acceptance and rejection.

Documents should be written for prototype, pre-series and series production phases. The production control plan should accompany each initial sample (for exceptions, refer to "Sample Trial Outline").

4.3.8 Initial Sample Tests

The supplier is approved or not approved for regular deliveries of a product with an article number on the basis of an initial sample test. Initial Sampling tests are mandatory in the following cases:

- an approved supplier delivers an article for the first time
- re-tested after article has failed to fulfill requirements for individual properties
- after changes to technical documentation for an article
- after tools have been changed or relocated
- after changes to supplier's manufacturing process
- (see Section 3.5.3.)

In the form called "Sample Trial Outline" Löwenstein specifies requirements for the Initial Sample Test Report (e.g. PPAP, EMPB), examinations and tests to be made and documents needed for a successful initial sampling.

Prescribed characteristics are to be tested on the basis of the technical documentation for the article.

Löwenstein provides the supplier with results of a cross-check of the Initial Sample Test Report.

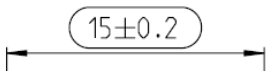
If no approval or special approval is given, the supplier receives the Sample Trial Outline containing additional information about variances and required corrective measures. If the article requires rework, Löwenstein and supplier define the type of rework, deadlines and costs. A repeated sampling trial may yield proof of defect-free manufacture and approval of regular deliveries.

When a sample trial has been completed and the supplier approved for regular deliveries, any subsequent complaints are to be written in a "Complaint Report".

4.3.9 Specially Labeled Specified Characteristics

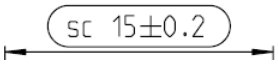
In order to make special requirements in Löwenstein specifications clear to everyone, different labeling conventions are used, which are explained in the following paragraphs along with their meaning and demands derived from them.

- Box around a measure for variable characteristic, e.g.,



Such labeling of measures indicates a test characteristic, which is taken into account during Incoming Goods Tests at Löwenstein. The same characteristic or attribute must be tested at an adequate point in the manufacturing process at the manufacturer's site. The scope of the test should be based on the manufacturing process, lot size and history of the part. Documentation of the test results should be provided where appropriate.

- Box around a measure for variable characteristic, with prefix [sc], e.g.,



or

- Prefix [sc] in brackets for text specifications, e.g., **[sc] Free of oil and grease**

  This label specifies a significant characteristic (sc = Significant Characteristic). Failure to fulfill such a requirement leads to disruptions in subsequent processes or breakdowns in devices from Löwenstein and can cause significantly high costs. There is no impact on safety and/or statutory provisions.

  This characteristic is taken into account during the Incoming Goods Test at Löwenstein. All internal or external documents (test plan, FMEA, control plan, etc.) must include this label.

This characteristic should be tested at a suitable point in the supplier's manufacturing process and statistically analyzed. The scope of the test should be based on the manufacturing process, lot size and history of the part.

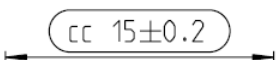
Requirement (for variable characteristic):

- During the initial sample test or relevant follow-up sample tests, statistical proof should be obtained on the basis of 100 values in tools with several cavities (minimum of 30/cavity but not fewer than 100 in total) that the critical short-term process capability index for [sc] characteristic ppk is ≥ 1.33.
- Deviations from this requirement are to be agreed to in writing prior to order placement. In addition to delivery of the initial sample test report/PPAP, confirmation of the capability index, respective individual measures and a histogram are to be sent. Furthermore, corresponding proof of the suitability of the MSA (Measurement System Analysis) utilized is to be submitted.
- During subsequent series production the critical process capability index for [sc] characteristic (cpk) has to be obtained for all production lots. This capability index should be cpk ≥ 1.00. The respective measurements and the capability index are to be documented and, upon request by Löwenstein, to be delivered. The qualified measurement system is to be used to obtain measurement values. If deviations occur, relevant measures are to be initiated. Parts from production lots in which the cpk index is below 1.00 may be delivered only with written approval from Löwenstein. Measures taken to satisfy the requirement again and evidence of supplier's success are to be documented in writing and, if requested, delivered to Löwenstein.

Requirement (for attributive characteristic):

- During the initial sample test or relevant follow-up sample tests, this characteristic has to be tested at an appropriate point in the supplier's manufacturing process. The scope of the test should be based on the manufacturing process, lot size and history of the part. The results are to be documented and information about test scope and results are to be delivered with the initial sample test report/PPAP (Production Part Approval Process) report.
- The scope of the test in the production run should be based on the manufacturing process, lot size and history of the part. Results are to be documented and, if requested, delivered to Löwenstein. Parts from production lots in which this requirement is not fulfilled may be delivered only with written approval from Löwenstein. Measures taken to satisfy the requirement again and evidence of supplier's success are to be documented in writing and, if requested, delivered to Löwenstein.

- Box around a measure for variable characteristic, with prefix [cc], e.g.,



or

- Prefix [CC] in brackets for text specifications, e.g.,
  [cc] Free of oil and grease

This label specifies a critical characteristic (cc = Critical Characteristic). Failure to fulfill this requirement can lead to a complete failure of a device. There is an impact on safety and/or statutory provisions.

This characteristic is taken into account during the Incoming Goods Test at Löwenstein. All internal or external documents (test plan, potential error cause and impact analysis, control plan, etc.) must include this label.

This characteristic should be tested at a suitable point in the supplier's manufacturing process and statistically analyzed. The scope of the test in the production run should be based on the manufacturing process, lot size and history of the part.

Requirement (for variable characteristic):

- During the initial sample test or relevant follow-up sample tests, statistical proof should be obtained on the basis of 100 values in tools with several cavities (minimum of 30/cavity but not fewer than 100 in total) that the critical short-term process capability index for [cc] characteristic is ppk ≥ 1.67. Deviations from this requirement are to be agreed to in writing prior to order placement. In addition to delivery of the initial sample test report/PPAP, confirmation of the capability index, respective individual measures and a histogram are to be sent. Furthermore, corresponding proof of the suitability of the MSA (Measurement System Analysis) utilized is to be submitted.
- The critical process capability index for [cc] characteristic (cpk) must be obtained for all production lots during all subsequent production runs. The capability index cpk should be ≥ 1.33. The respective measurements and the capability index are to be documented and, upon request by Löwenstein, to be delivered. The qualified measurement system is to be used to obtain measurement values. If deviations occur, relevant measures are to be initiated. Parts from production lots in which the cpk index is below 1.33 may be delivered only with written approval from Löwenstein. Measures taken to satisfy the requirement again and evidence of supplier's success are to be documented in writing and, if requested, delivered to Löwenstein.

Requirement (for attributive characteristic):

- During the initial sample test or relevant follow-up sample tests, this characteristic has to be tested at an appropriate point in the supplier's manufacturing process. The scope of the test in the production run should be based on the manufacturing process, lot size and history of the part. The results are to be documented and information about test scope and results are to be delivered with the initial sample test report/PPAP (Production Part Approval Process) report.
- The scope of the test in the production run should be based on the manufacturing process, lot size and history of the part. Results are to be documented and, if requested, delivered to Löwenstein. Parts from production lots in which this requirement is not fulfilled may be delivered only with written approval from Löwenstein. Measures taken to satisfy the requirement again and evidence of supplier's success are to be documented in writing and, if requested, delivered to Löwenstein.

4.3.10 Additional requirements

Oil-and grease free

In general there are special requirements according the cleanness of purchased components which are assembled within our medical devices. These requirements are mentioned in our technical specifications or in within the order text. The requirement is to be understood as follows:

- For all parts which are in direct contact with pressurized oxygen the standard DIN 15001, the pressure range and the max. quantity of remaining dirt is mentioned in the specification or in the order text
- For all other parts is mentioned in the specification “free of contamination and manufacturing related chemicals like e.g. coolants, release agents or lubricants”.

In case of something is not clear at all please contact your strategic purchaser.

Wipe proof according standard DIN EN 60601-1

- A soft, clean wiping tissue soaked with alcohol has to be wiped over the printing of the component with light pressure for 15 seconds. Repeat this for 5 times. Dry the component with a clean cloth. Check the surface visual. The printing must clearly readable. No other damages are allowed.
- Repeat the test with Isopropanol and Gigasept FF.

Usage of special external standards

- For our suppliers of electronic components the IPC guidelines apply to the manufacture along to the state of the art
  - IPC-A-600 class 2 for printed circuit boards (PCB)
  - IPC-A-619 class 2 for printed circuit boards assembled (PCBA)
  - IPC-4101 for the base material of PCB
  - IPC-SM840 for solder stop paste
- Components and packaging have to be delivered in accordance to the actual European requirements (EG) No. 1907/2006 (REACH) and Guideline RoHs-II (2011/65/EU). The required information must be strictly observed.

  List of banned substances http://echa.europa.eu/web/guest/candidate-list-table

4.4 Quality Assurance in Series Production

4.4.1 Quality Assurance at our Suppliers' Sites

Test plans, production control plan and test instructions are to be followed. Test results are to be documented and archived for at least 16 years.

4.4.2 Incoming Goods Tests at Löwenstein

Löwenstein conducts an Incoming Goods Test for every purchased series product with an article number. Variances to this procedure are to be arranged as needed in a quality assurance agreement.

4.4.3 Complaints about Delivery

Complaint Report

Detected defects are captured in the form "NCR, Non-Conforming Report", which is sent to the supplier. Among other things the report includes:

- an exact description of the detected defects
- Decisions, costs, if rework or sorting is required, number of rejects and number of approved items

If Löwenstein decides that corrective action is required, the supplier will be told to inform Löwenstein in writing (8-D Report) of the causes of the error and corrective actions taken to eliminate the causes.

A processing fee of 100 Euro is charged for a complaint report to cover the additional effort (report creation, separating of NOK parts, feedback to analysis (of the 8-D report), support provided by Strategic Purchasing and R&D, handling of return deliveries, remedial actions, etc.).

Clarification of Complaint with Supplier

The Operational Purchaser and a Quality Assurance employee can clarify any further procedures involving rework, return delivery, new delivery, costs, deadlines, error causes and corrective measures with the supplier.

As a rule Löwenstein prefers to return defective parts and components to the supplier.

If a need arises for operational reasons (production standstill, inability to delivery, conventional penalties, etc.), Löwenstein may perform appropriate rework and charge the supplier without obtaining prior approval.

4.4.4 Monitoring of delivery performance (quality wise)

To ensure an optimal continuous improvement process for our products we are rely on the quality data of our suppliers. Therefor every of our suppliers has document the relevant data of his test- and check procedures. These data must be analyzed and in case of deviation to the expected result the supplier has to define appropriate actions. Complaints of Löwenstein have to be comparing with this data base to detect potential test- or check gaps, to have the possibility to verify implemented actions or to get an early indication about a general weakness of the manufacturing process or the design of the component/product. In the latter case Löwenstein shall be informed urgently!
Quality data will be requested by Löwenstein on irregular base or due to special incident.

In the moment the following section is only valid for our supplier of electronic goods!

Löwenstein is expecting following data from our supplier every quarter of the year:

- A bar diagram with at least 20 of the most happened problems/failures in absolute numbers. Problems/failures of internal processes at supplier site should also take under consideration as the data of returned goods (NOK parts our of Löwenstein complaints).
- An overview of the above mentioned problems/failures in relation to each individual article number and the point of origin of each problem/failure (e.g. internal process, sub-supplier process, customer complaint, etc.). For each article number the analyzed root cause, the individual serial number and maybe some additional information are necessary, too.

According an internal Löwenstein procedure these data will be analyzed by an employee of the R&D department. The main aspect is not only the absolute number of NOK articles also the failure mode will be part of this assessment (e.g. design failure of Löwenstein, test failure or test gap, serial failure, etc.)

The result of these analyses will compared with the data of the Löwenstein customer complaints to recognize potential worse market situations in an early stage.

Base on all of these data Löwenstein will raise corrective or preventive action in a prioritized way. The supplier has to be involved in an appropriate matter of his responsibility or his possibilities.

The regular submitted quality data will used to verify the success of implemented actions.