QUALITY GUIDELINES FOR SUPPLIERS TO THE **PARI** CORPORATE GROUP

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1 INTRODUCTION

1.1 General

Our mission is to improve the lives of those affected by respiratory diseases and those who provide care for them. This is reflected in our comprehensive portfolio of innovative products.

With this in mind, the PARI corporate group has established a quality management system in accordance with EN ISO 13485, and only uses high-quality products from external suppliers. Accordingly, the quality of PARI products is influenced to a significant degree by the quality and reliability of the products supplied. Suppliers therefore play an important role in fulfilling our customers' expectations.

1.2 Aims and objectives

Because suppliers play such an important role in product quality, it is essential to evaluate suppliers not only in terms of quality capability, pricing and delivery capacity, but also, for example, their compliance with hygiene and environmental standards.

It is the objective of the PARI corporate group to only enter into supply relationships with, establish collaborative partnerships with and develop quality-assured suppliers.

These quality guidelines define the general quality assurance requirements that must be fulfilled by suppliers to the PARI corporate group. The guidelines form part of supplier contracts and are therefore binding for suppliers. The supplier undertakes to inform its subcontractors about the relevant requirements from these guidelines or to specify its own requirements for subcontractors in order to ensure that the requirements set out in these guidelines are fulfilled.

The PARI corporate group reserves the right to conclude a general service agreement with the supplier based on these quality guidelines, with specific requirements relating to process and product quality to the extent that such additional specifications are required.

1.3 Scope

These guidelines apply to all suppliers that supply products to the PARI corporate group (PARI Medical Holding, PARI, PARI Pharma, PARItec).

In the context of these quality guidelines, products refer to:

- raw materials and intermediate goods that are ordered by the PARI corporate group and influence the quality of the finished products
- finished products that are ordered by and to be sold by the PARI corporate group (e.g. OEM products)

2 SUPPLIER QUALIFICATION

2.1 Supplier selection, approval and evaluation

The PARI corporate group only procures products and services from qualified and approved suppliers. Suppliers are approved subject to their successful completion of a defined supplier selection procedure, which may include a quality evaluation and a supplier audit.

In the case of deliveries for production, the products delivered are subject to quality inspection on a regular basis using random sampling and in accordance with the quality procedures used by the PARI corporate group. The purpose of these inspections is to verify whether the products delivered fulfil specific requirements. The results of these inspections are incorporated into the supplier evaluation, for example.

The supplier evaluation provides the PARI corporate group with a statement of the supplier's quality capabilities. Suppliers that supply „critical products or services" are evaluated as a matter of principle.

These „critical products or services" are those that could pose a risk to users in the event of a deviation from specified values. In addition, the Purchasing department of the PARI corporate group may define suppliers as „strategic suppliers". „Strategic suppliers" are also subject to supplier evaluation.

Supplier evaluation occurs at least once each financial year.

It places suppliers in one of the categories from A to D.

A-rated suppliers are preferred suppliers for new projects and strategic partnerships; B-rated suppliers are considered reliable partners with the potential for improvement, which is to be discussed with them; C-rated suppliers are contacted and measures to improve quality are agreed; D suppliers are informed and partnership with these is dissolved as soon as possible.

2.2 Supplier audit

In the interests of joint quality assurance, the PARI corporate group reserves the right to conduct audits at the supplier site at any time. The supplier will receive advance notification of these.

Based on the Recommendation of the European Commission published on 24 September 2013, notified bodies in the field of medical devices should carry out unannounced audits in addition to product assessments and quality system assessments.

The authorities or the Notified Body responsible for PARI are entitled to conduct unannounced audits at the supplier site or the sites of the supplier's subcontractors at any time during normal business hours.

Compliance with legal and regulatory requirements and product safety will be verified as part of these audits.

The supplier must agree these rights of access and inspection in writing with its own external suppliers and subcontractors.

2.3 Supplier development

The definition of specifications, the exchange of data from the goods receipt inspection, the supplier evaluation and the results of supplier audits are intended to foster collaborative partnerships and to provide suppliers with guidance on their potential for development and improvement. The prime objective of supplier development is to ensure the continuous and complete compliance of suppliers with all expectations of the PARI corporate group.

3 MANAGEMENT SYSTEMS

The PARI corporate group has implemented the requirements for medical technology as set out in ISO 13485 in its quality management system and has been certified in accordance with this standard.

Based on this standard of quality, PARI suppliers must, as a minimum requirement, observe the requirements set out in DIN EN ISO 9001 and implement these within their organisation. Furthermore, suppliers should aspire to implementing a QM system in accordance with the currently valid version of ISO 13485.

4 QUALITY AND ENVIRONMENTAL POLICY

The quality policy of the PARI corporate group specifies that all products are manufactured using state-of-the art technology and the latest scientific knowledge, and that they fulfil all customer and quality requirements. Product safety is defined as the top priority in this policy.

The conservation of our natural environment and ensuring the ability of future generations to meet their own needs, the protection of jobs and the continuous improvement of working conditions are of the utmost concern to the PARI corporate group.

Environmentally-aware and prudent use of energy and raw materials is a core element of all processes and products of the PARI corporate group. This philosophy must be observed and implemented by our suppliers.

5 PROCESS AND PRODUCT QUALITY

5.1 Requirements for supplier process quality

A high level of process control and capability on the part of the supplier provides a basis for ensuring compliance with the defined product requirements. It also provides a basis for meeting agreed targets in terms of quality, deadlines and costs.

The supplier must determine, monitor and control the capability of all processes and production facilities and to improve these on an ongoing basis.

The supplier must validate critical processes where the results can only be verified by testing the product at a later point in time or cannot be verified at all. These processes must be monitored and controlled in accordance with the specific process situation. In the case of critical processes, the PARI corporate group may define and demand compliance with special requirements relating to validation and risk management.

A conformity declaration must be issued on the delivery note or must accompany the delivery (with reference to the delivery, articles, article numbers etc.) in order to document the necessary inspections and the quality of the products.

Documentation must exist to certify that all employees involved in these processes are suitably qualified and have received appropriate training. The documentation required for these processes, the production facilities used and the employees involved must be clearly and unambiguously distinguishable.

Processes that are controlled using statistical process control (SPC) must comply with current industry standards in terms of process capability. Measuring systems must also be qualified and calibrated. Proof of machine, process and measuring system capabilities, as well as the relevant control and process plans, must be submitted to the PARI corporate group upon request.

5.2 Requirements for the quality of products to be supplied

The supplier is obliged to deliver defect-free, legally compliant products (e.g. compliant with the Directive on CE marking, with REACH or RoHS) as ordered. Furthermore, the quality characteristics specified by the PARI corporate group in accordance with our „zero-error strategy“ must be implemented and verified. The supplier assumes full responsibility for the quality of the products to be delivered and the products delivered. The features of the products to be delivered, as well as general requirements, are defined in quality documentation. In this context, quality documentation refers to:

- Drawings

- Data sheets
- Specifications
- User requirements specifications and functional specification documents
- Quality agreements, general service agreements
- Supplier documentation created at the behest of or in collaboration with the PARI corporate group
- EU Directives
- International and/or national norms and regulations
- GMP guidelines

The supplier receives the documents required from the Purchasing department of the PARI corporate group. The supplier takes appropriate measures to ensure that products are always manufactured and delivered in accordance with the currently valid technical documentation.

Products delivered in a defective state are taken into account in the quality assessment. This, in turn, forms part of supplier evaluation.

If the supplier detects defective products during the supplier's own inspections, it is the responsibility of the supplier to immediately remove these from the batch, analyse the cause of the defect and implement corrective actions.

5.3 Quality assurance in relation to subcontractors

The supplier must ensure that products procured from subcontractors fulfil the agreed quality requirements. The necessary quality assurance measures include sampling and approval procedures, as well as goods receipt and goods issue inspections.

The supplier must ensure that documentation requirements relating to the contents of bought-in parts are fulfilled, and that the relevant data sheets are made available to the PARI corporate group.

5.4 Risk management

The supplier must use appropriate risk management measures to ensure that process risks are identified and minimised. If critical weak points are identified, corrective and preventive actions must be initiated immediately. The results of risk analyses can, where necessary, be requested and inspected by the PARI corporate group.

5.5 Hygiene

As a manufacturer of medical devices, rigorous hygiene requirements have been established within the PARI corporate group. These requirements are reflected in all processes and products of the PARI corporate group. The PARI corporate group similarly demands of its suppliers that they guarantee a certain standard of hygiene appropriate to the production site in order to ensure the required product quality.

If necessary, detailed hygiene requirements will be defined in collaboration with the supplier as part of a quality agreement or general service agreement.

6 INITIAL SAMPLE

6.1 Submission of an initial sample

The supplier is obliged to promptly submit an initial sample of the product to the PARI corporate group prior to the commencement of regular deliveries for production in each of the following cases (but not where the items delivered are catalogue goods or standard parts):

- new products or changes to products
- changes to technical documents
- changed manufacturing processes or new tools
- relocation of production

Initial samples must be manufactured under serial production conditions and must be inspected on the basis of all quality characteristics required according to the technical specifications. Together with the initial samples, the supplier must deliver a complete „Initial sample test report“ (ISTR) containing the results of these inspections. Deliveries of initial samples must be clearly marked „INITIAL SAMPLE“ on the packing unit and on the delivery note. The supplier will receive a pilot order (with an order number starting with 48...) from the Purchasing department of the PARI corporate group for the production of the first product shipment. Similarly, the first delivery following a change must be marked with „FIRST DELIVERY after change“ and the number of the pilot order must be specified on each packing unit and on the delivery note. The number of samples required is defined in the pilot order on a case-by-case basis. In the case of multi-cavity moulds, samples from each cavity must be measured and delivered separately. The PARI corporate group inspects samples and either approves them for delivery for production or rejects them. In justified exceptional cases, an initial sample may be delivered without a corresponding report in consultation with the PARI Quality department. In such cases, the initial sample is inspected by the PARI corporate group at the expense of the supplier.

6.2 Approval for delivery for production

Delivery to the PARI corporate group for production purposes can only begin after the initial sample has been approved. Initial samples are either approved or rejected in the initial sample inspection report that is sent by the PARI Quality department to the supplier. Any special approvals must similarly be made in writing by the PARI Quality department, and must be applied for in advance by the supplier.

7 Delivery for production

Deliveries for production must comply in their entirety with the quality documentation and with the approved initial samples, the order, the delivery conditions, the packaging standards (where applicable) and with legal requirements.

The deliveries must meet the standard of state-of-the art technology and be free of manufacturing defects of any type that affect processing and performance characteristics or appearance.

The supplier must select packaging that will prevent any shipping damage or corrosion. Special packaging requirements are specified in the order or in the quality documentation. Each packing unit must be identified by the article number and quantity, which must be visible from the outside. Any additional requirements, such as the serial number or batch number, date of manufacture or inspection mark, will be specified in the order or in the quality documentation.

8 PROCEDURE IN THE EVENT OF CHANGES/DEVIATIONS

8.1 Changes by the PARI corporate group

The Purchasing department of the PARI corporate group will notify the supplier of changes to products or quality documentation. All further communication and documentation must include a reference to the TW number specified in the change notification. The supplier must then proceed as described in Section 6.1 „Submission of an initial sample".

8.2 Changes by the supplier

If the supplier or the supplier's supplier is intend to make a change to a product, process or service, the supplier must immediately notify the Purchasing department of the PARI corporate group in writing for approval.
The reported change request is then inspected and evaluated. The supplier will subsequently be informed of the decision and of any documentation required as proof by the Purchasing department of the PARI corporate group. Any deviation from the quality documentation of the PARI corporate group is not permitted without the prior written approval of the PARI corporate group. Following approval, the supplier must proceed as described in Section 6.1 „Submission of an initial sample".

9 PRODUCTS IDENTIFIED AS NON-COMPLIANT

Complaints and objections on the part of the PARI corporate group will be sent in writing to the supplier. An initial response from the supplier must be filed within 48 hours. An action report (e.g. an 8-D report) must be sent to the PARI Quality department as soon as possible. The PARI corporate group reserves the right to return the complete shipment about which the complaint has been made to the supplier. Further actions will be defined on a case-by-case basis by the PARI corporate group. These may include a comprehensive inspection by the supplier of all stock of the affected product that is currently held by the PARI corporate group. In urgent cases, the PARI corporate group may, in consultation with the supplier or until such time as the supplier arrives at the PARI site, conduct this inspection using PARI employees or external contractors at the supplier's expense in order to ensure continued production.

If, under exceptional circumstances, products need to be delivered that do not fully comply with the quality documentation, the supplier must obtain an exemption in writing (special approval) from the Purchasing department of the PARI corporate group prior to delivery. If deviations are subsequently detected, the PARI corporate group must be informed immediately.

10 DOCUMENTATION

Documentation refers to all information, including carrier media (e.g. process descriptions, work and inspection instructions, specifications, drawings, batch documentation etc.) that are required for the manufacturing and quality assurance of the products to be delivered.

Unless otherwise specified in a quality agreement or general service agreement, the supplier must store this documentation for a period of at least 10 years following the delivery of the last product and, if necessary, make it available to the PARI corporate group.

In particular the documentation relating to tests during the manufacturing process must always be archived by the supplier so that it can be submitted to the PARI corporate group at any time in the event of queries or if it is necessary to furnish proof that the products delivered as part of delivery for production are identical to the initial sample provided.

11 CONFIDENTIALITY

Documentation created and knowledge derived in connection with this agreement must only be used for the aims and objectives set out in this agreement. They are to be treated with the same care as the supplier's own documents. They must not be disclosed to third parties if they are classified by the PARI corporate group as „confidential" or if the latter has an obvious interest in ensuring that they remain confidential. In this case, a non-disclosure agreement will be concluded with the supplier.

12 NOTES

If the supplier is unable to fulfil one or more of these guidelines, the supplier must notify the Purchasing department of the PARI corporate group in writing. The supplier will then be instructed as to how to proceed.

13 ACKNOWLEDGEMENT OF QUALITY GUIDELINES BY THE SUPPLIER

By signing below, the supplier acknowledges the quality guidelines set out in this document.

Suppliers that fail to acknowledge these guidelines will be blocked by the Purchasing department and will be replaced as soon as possible.

Company: .....

Last name: ..... First name: .....

Date .....

Signature .....

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