# 1 Contents

## 2 Preamble

The Richard Wolf Group is a full-service provider in the field of endoscopy, offering a range of highly innovative instruments and system solutions for minimally invasive procedures. The quality and reliability of those who supply products, software, and services (hereinafter referred to as “products”) have a significant impact on the quality of the products made by the Richard Wolf Group, so suppliers have a key role to play in meeting customer expectations. In the interests of ensuring that customers are satisfied and that binding official and regulatory requirements are complied with, the Group can only work with suppliers who meet strict quality demands.

## 3 Purpose of this guideline

This guideline is intended to safeguard product quality, optimize cooperation between partners, and ensure that, by working together, all parties can satisfy constantly rising market expectations in terms of product safety, performance, and conformity.

The guideline lays down the **fundamental quality requirements** that suppliers must meet in order to achieve these outcomes.

The Richard Wolf Group reserves the right to agree further regulations with suppliers, covering specific requirements in terms of process, product, and service quality, or regulatory requirements, based on this quality guideline as needed.

## 4 Scope

This guideline applies to all processes outsourced by the Richard Wolf Group (Richard Wolf GmbH, RIWOSpine GmbH, Kurt Semrau GmbH, Wintegral GmbH, Kurt Heynemann GmbH, or another German company affiliated with them under the terms of Section 15 et seq. of the German Stock Corporation Act) (hereinafter referred to as the Customer); that is, it applies to each supplier (hereinafter referred to as the Supplier) who delivers products or provides services to the Customer. It regulates requirements regarding how Suppliers are selected and orders are processed.

**If this guideline contains quality assurance and quality control provisions for Suppliers, they apply to every order placed by the Customer and the Supplier acknowledges these provisions each time it accepts an order for its products.**

The guideline complements any agreements that are already in place between the Customer and the Supplier.

## 5 Terms and definitions

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| Products | Medical devices, assemblies, and components of medical devices, as well as the associated raw materials or services, plus software. |
| Critical products[1] | This refers to products that, should they deviate from specifications, could lead to an unacceptable risk for the patient, the doctor, or other parties, or could significantly impair performance. |
| Critical Suppliers | Suppliers of critical products. This may also include providers of regulatory services (e.g., auditors or representatives). |
| Specification | This refers to the requirements the Customer lays down for the product (e.g., requirement specification, drawings, data sheet, testing and packaging requirements; validations, regulatory requirements, performance specifications, acceptance criteria, quality assurance documents, EU Directives and Regulations; Medical Device File, etc.). |
| MDD 93/42/EEC | Council Directive 93/42/EEC of June 14, 1993, concerning medical devices (Medical Devices Directive) |
| MDR | Medical Device Regulation MDR 2017/745 (EU Regulation concerning medical devices) |

This document also uses the terms found in the relevant standards and statutory rules and regulations (EN ISO 9001:2015, EN ISO 13485:2016, MDR, and FDA 21 CFR 820).

## 6 Compliance, implementation, deviations

1. The Supplier is responsible for ensuring compliance with and implementation of this guideline (including by its subcontractors). The Supplier undertakes to ensure that any subcontractors it commissions also comply with this guideline.

[1] Critical products can include (see ZLG 3.9 B17):
- Medical devices (finished products)
- Primary packaging (usually of the medical device)
- Sterilization
- Laboratories (e.g., biocompatibility)
- Services (design, distribution, compliance with statutory regulations, etc.)
- Regulatory labeling
- Other similar instances where the actions of the Supplier have a significant impact on the conformity of the finished medical device and the Customer cannot provide proof of the Supplier having performed sufficient inspections

2. The Supplier shall act immediately to notify the Customer (purchasing department) in writing of any deviation from this guideline. This notification shall be submitted via email to ze@richard-wolf.com or fax to +49 7043 35-4133.

## 7 Supplier credentials, product specification, order processing

1. The Customer only purchases products from suitably qualified and approved Suppliers. Suppliers are approved if they pass a Supplier selection procedure defined by the Customer, which may include a Supplier audit.

2. As part of the Supplier selection procedure (inquiry and bid phase), the Customer and the potential Supplier shall agree on the **product specification** and record this in writing. It is essential to consider the requirements of the MDR here.

3. During order processing (Customer purchase orders, Supplier order confirmations, Supplier delivery notes, Supplier testing certificates or certificates of conformity), the Customer and the Supplier shall refer to the product specification. The same shall apply to the complaints process (Customer quality notifications, Supplier 8D reports), the change process (Product Change and Product Termination Notifications from partners), and, where necessary, the post-market surveillance (PMS) process.

4. The Supplier's subsequent performance shall be monitored continuously and be adequately and objectively assessed accordingly.

## 8 Critical products and Critical Suppliers

1. The Customer shall conduct a risk assessment on the Supplier product and verify whether it is a critical product. This assessment is usually carried out when the Customer's medical device undergoes qualification, or as soon as the Customer obtains information that enables them to classify the product.

2. Especially if the Customer risk assessment results in the Supplier product being deemed a critical product, the Supplier shall ensure that the requirements contained in Recommendation 2013/473/EU of the European Commission on unannounced audits are supported and implemented by the following means:

   a) Ensure that the necessary preparations have been made for conducting audits on the Supplier's premises, specifically

      - Study and implement Recommendation 2013/473/EU of the European Commission
      - Provide information and instruction to the persons concerned about the content and procedure of the unannounced audits
      - Develop a procedure for organizing unannounced audits in the Supplier's company
      - Ensure the availability of up-to-date technical documentation at all times
      - Ensure the availability of all (in-process) test reports at all times, including for processes carried out by key subcontractors
      - Ensure that the requirements contained in Recommendation 2013/473/EU of the European Commission are implemented by key subcontractors of the Supplier and that proof of said implementation is made available upon request by the Customer

b) The Supplier shall notify the Customer at least three months in advance of any periods when an unannounced audit would not be possible (e.g., because the products being certified are not manufactured during this time; due to a vacation shutdown; and so on).

This notification shall be submitted in writing via email to ze@richard-wolf.com and fax to +49 7043 35-4133.

c) If an unannounced audit cannot be conducted due to the Supplier not submitting a notification of such periods, or submitting a notification too late, the Supplier shall reimburse the additional expenditure accrued by the Customer as a result.

d) In the event of an unannounced audit, the audit team from the notified body/authority is required to start the audit at the latest 30 minutes after arrival on the Supplier's premises. If this is not possible, it could lead to the termination of the audit.

e) If the Supplier or a subcontractor refuses to cooperate with unannounced audits and if an announced audit therefore cannot be conducted either on time or at all, the Customer shall be entitled to terminate the contract without notice and to claim damages, where applicable.

3. In line with its legal obligations, the Customer shall report the name and contact details of the Critical Supplier, as well as details of critical products (including descriptions of how they are manufactured or how services are performed), to the Customer's notified body and/or the relevant authority. The same shall apply to the Supplier's critical subcontractors. This is necessary for the purposes described in Item 7.2.

4. Supplier monitoring and assessment:

   Critical products and Suppliers are therefore subject to continuous and ongoing monitoring to ensure the safety, performance, and conformity of the products. The details of this can be specified separately.

## 9 Certification status

1. The Supplier shall submit copies of its QM system certificates to the Customer during the course of the Supplier qualification process or its ongoing working relationship with the Customer. The same shall apply to the accreditations or certificates of relevant subcontractors.

2. If appropriate and required by regulations as a condition of working together, the Supplier shall ensure that it holds the relevant (EC) Declarations of Conformity from a notified body/authority. The Supplier shall also provide the Customer with a copy of the (EC) Declaration of Conformity where applicable. The details of this can be specified separately.

3. The Supplier shall maintain the certificates/declarations for the duration of the working relationship.

4. If, under exceptional circumstances, the Supplier does not follow a certified quality management system, it shall nevertheless follow a quality management system according to internally defined regulations that safeguard product quality. The Supplier shall provide the Customer with a description of these regulations unprompted and shall entitle the Customer to audit its system even prior to the first delivery, where applicable.

## 10 Changes to the QM system and the certification status

The Supplier shall notify the Customer of any change to its quality management system before it is implemented, if said change could affect manufacturing and delivery processes, whose quality must be assured, or the quality of the actual products. The Supplier shall report changes to its certification and/or accreditation status or changes to relevant (EC) Declarations of Conformity to the Customer's notified body/authority immediately in writing. The Supplier shall also submit renewed or reissued certificates unprompted and without delay. The Supplier shall ensure that its subcontractors comply with the same.

## 11 Process and product quality

### 11.1 Process quality (verification and validation)

1. The Supplier shall describe and document all the relevant processes and procedures, in particular those associated with quality assurance, relating to the production or the provision of services in question.

2. The Supplier shall validate all processes relating to production and the provision of services for which the result is not verified or cannot be verified by means of subsequent monitoring or measurement, meaning that any shortcomings only become apparent once the product has been placed in use or the service has been provided. The validation must demonstrate the ability of these processes to consistently achieve the planned results.

3. A system of standardized ongoing monitoring and inspection of the products at the end of the manufacturing process (final inspection) shall be introduced and documented for any processes which cannot be validated. Verification and validation/revalidation procedures, including documentation of records, must be defined in writing in the Supplier's quality management system.

4. The Supplier shall follow an appropriate risk management system to ensure that process risks are identified and minimized. If critical weak points are identified, corrective and preventive measures must be introduced immediately.

5. Processes shall be designed so the products are delivered free of any contamination associated with the production process, unless agreed otherwise. The cleaning processes carried out by the Supplier shall be validated and documented in accordance with the state of the art. Product-specific further requirements made by the Customer regarding the cleanliness of products shall be implemented, validated, and documented accordingly by the Supplier.

## 11.2 Product quality

1. When executing orders, the Supplier shall ensure that the products:

   a) are in conformity with the specification;

   b) are free of other defects or errors that render the product worthless or useless, or that limit its value or its suitability to perform as expected or as laid down in the contract;

   c) comply with the state of the art/good engineering practice and meet the applicable statutory and official requirements (including those found in EU Directives and EU Regulations);

   d) are free of legal defects; and

   e) are provided with the process quality described in Item 11.1 properly delivered.

## 11.3 Quality inspections/acceptance criteria

### 11.3.1 First samples

1. The Supplier shall deliver clearly labeled first samples of the product, together with a test report at no additional charge, on receipt of a corresponding order from the Customer. The first samples shall be manufactured using production tooling under series conditions. The Customer shall inspect the samples and approve or reject the product for series delivery.

2. In the following instances (with the exception of catalog goods and standard parts), the Supplier shall provide the Customer with first samples in good time before commencing series delivery:

   - New products or changes to existing products
   - Changes to the specification that could affect quality
   - Changed production processes or new tools

- Production relocation

#### 11.3.2 Supplier quality inspections/Customer's acceptance criteria/quality assurance documents

1. Before the products are delivered, the Supplier shall take appropriate measures to ensure that the products meet the requirements described in Item 11 and are only delivered in an inspected version, and that a corresponding certificate of conformity (e.g., Supplier's declaration of conformity according to DIN EN ISO 17050-1) is submitted to the Customer. Further details can be specified separately.

2. The Supplier shall maintain records regarding the performance of quality assurance measures and retain these records and any samples of the products to be delivered in a clearly organized manner. The Supplier shall grant the Customer access to the extent required, explain the records, and hand out copies of the records and any samples.

### 11.4 Traceability

1. The Supplier shall warrant that every batch or production order is fully and seamlessly traceable and documented at all levels, from semi-finished products, to component or accessory parts, through to the finished end product. The Supplier shall ensure that any specific faulty products, accessory parts, or semi-finished products can be isolated at any time.

2. The Supplier shall record appropriate details relating to the batch or serial number in its delivery documents or proofs of performance.

3. The Supplier shall observe and implement the requirements contained in the Customer's specifications.

### 11.5 Employee credentials

1. The Supplier shall ensure that all persons conducting work that relates to quality have a qualification appropriate to this work and that records proving employees have suitable education, training, and experience are maintained. The Supplier shall ascertain and document its employees' current level of knowledge and training needs, provide appropriate training in line with a set procedure, and ensure that the training provided is effective.

2. The Supplier shall observe and implement the relevant requirements contained in the agreed specifications.

### 11.6 Infrastructure and working environment

1. The Supplier shall determine, provide, and maintain the necessary infrastructure and working environment, and comply with the stipulated maintenance cycles. The Supplier shall document its resource management processes accordingly and – at the request of the Customer – shall present suitable documents to demonstrate this without delay.

2. The Supplier shall observe and implement the relevant requirements contained in the agreed specifications.

### 11.7 Storage and transport

1. The Supplier shall ensure that the infrastructure used for storing the products meets the relevant storage conditions. Generally speaking, the products must be stored and handled

securely and safely (e.g., stored somewhere that is clean, dry, and within the required temperature range). The same applies when products are being transported. In this case, the Supplier shall ensure that the relevant transport conditions are met. Particularly for products whose safety and performance largely depend on the relevant storage and transport conditions being met, the Supplier shall implement European Commission Guideline 2013/C343/01 on Good Distribution Practice of medicinal products for human use as appropriate.

2. The Supplier shall observe and implement the relevant requirements contained in the agreed specifications.

### 11.8 Subcontractors

1. If the Supplier procures production or test equipment, software, services, materials, or other pre-deliveries from subcontractors for the development, production, or quality assurance of products, it shall specify these in its quality management system for the purposes of this guideline, or take suitable measures itself to ensure the requisite quality of the pre-deliveries.

2. The Supplier's subcontractors are deemed to be its vicarious agents. The Customer is entitled to request full details about subcontractors from the Supplier (in accordance with MDR requirements), as well as proof that the Supplier has inspected its subcontractors' quality management systems and is satisfied they are effective for the long term.

3. The Supplier shall work together with its subcontractors to draw up all the contractual regulations necessary for fulfilling the obligations arising from this guideline.

4. The Supplier shall observe and implement the relevant requirements contained in the agreed specifications.

## 12 EU Regulations/EU Directives/EU Recommendations

### 12.1 EU Recommendation 2013/473/EU

Within reasonable efforts, the Supplier shall provide adequate and objective support to the Customer in implementing the requirements deriving from the European Commission Recommendation 2013/473/EU on the audits and assessments conducted by notified bodies concerning medical devices.

### 12.2 Medical Devices Directive 93/42/EEC (MDD 93/42/EEC) / EU Regulation 2017/745 (MDR)

1. The Supplier shall manufacture and supply the products – provided these are medical devices – in accordance with the Medical Devices Directive 93/42/EEC (MDD 93/42/EEC) and take product-related and documentation-related requirements of the Customer into consideration.

2. At the latest following the phasing-out of the MDD 93/42/EEC and the commencement of Regulation (EU) 2017/745 dated April 5, 2017 concerning medical devices (MDR), the Supplier shall manufacture and supply the products in accordance with this regulation, take product-related and documentation-related requirements of the Customer into consideration, and also ensure that no disadvantages arise for the Customer in connection with the switch to this regulation.

3. The MDR requires complete technical documentation, including that relating to processes outsourced by the Supplier. The Supplier shall provide adequate and objective support in implementing MDR Annex II, Section 3 DESIGN AND MANUFACTURING INFORMATION and shall submit the required documentation to the Customer.

4. The same shall apply universally to further requirements of the MDR (e.g., post-market surveillance or PMS), which may not have been previously defined in MDD 93/42/EEC, or to new, extended requirements laid down by the notified body or the relevant authority. In all cases, the Supplier shall provide the Customer with adequate and objective support.

## 12.3 Regulation (EC) No. 1907/2006 (REACH)

1. The Supplier shall ensure that the delivered products fulfill Regulation (EC) No. 1907/2006 (REACH). The Supplier shall fulfill all existing obligations regarding notification, approval, registration, and authorization in accordance with this regulation. If obligations are placed on the Customer as a result of the Supplier failing to fulfill its obligations correctly, the Supplier shall, at first request, indemnify the Customer against any costs incurred in this regard, unless the Supplier is not responsible for the fact that the obligations have not been correctly fulfilled.

2. Furthermore, the Supplier shall make the safety data sheets required in line with Regulation (EC) No. 1907/2006 (REACH) available to the Customer prior to the first delivery without being prompted to do so.

3. For deliveries into or within the European Union (EU), the Supplier shall meet its communication obligations pursuant to Article 33 of Regulation (EC) No. 1907/2006 (REACH), whereby every Supplier of a product must inform the purchaser of any substance listed in accordance with Article 59 (Candidate List of SVHC). The Candidate List of SVHC is continuously updated by the European Chemicals Agency and is available at https://echa.europa.eu. The Supplier shall keep up to date with the latest information provided on this website and shall meet its communication obligations toward the Customer. If the Customer prescribes materials which do not meet the conditions laid down in Regulation (EC) No. 1907/2006 (REACH), the Supplier shall inform the Customer immediately.

## 12.4 Regulation (EC) No. 1272/2008 (CLP)

The Supplier undertakes to fulfill its obligations concerning labeling, packaging, and communication for the delivered products, in particular in accordance with Regulation (EC) 1272/2008 (CLP), in full, in good time, and without further prompting.

## 12.5 EU Directives – 2011/65/EU (RoHS) / 2012/19/EU (WEEE)

1. Furthermore, the Supplier shall warrant compliance with the requirements of Directive 2011/65/EU on the restriction of hazardous substances (RoHS) and Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), as well as the requirements of national implementations in Germany, in particular the Ordinance on Hazardous Substances in Electrical and Electronic Equipment (ElektrostoffV) and the Electrical and Electronic Equipment Act (ElektroG).

2. The Supplier must declare that the contract products are RoHS-compliant in writing to the Customer prior to the first delivery, label the packaging of the products accordingly, and

confirm the products are RoHS-compliant by including the information “RoHS-compliant” in the delivery note or elsewhere in the certificates of conformity.

### 12.6 New EU Regulations/Directives/Recommendations

If in future the EU should issue new or modified Regulations/Directives/Recommendations, which are relevant to the business relationship between the Customer and the Supplier, the Supplier shall implement them as well. The EU Regulations/EU Directives/EU Recommendations stated above shall therefore not be considered exhaustive.

## 13 Supplier documents

1. The Supplier shall assist the Customer to create technical documentation and maintain the verification records it needs to meet the essential safety and performance requirements contained in Annex I of Directive 93/42/EEC and Annex I of the MDR.

2. The Supplier shall make available to the Customer all the requisite documents and records, which the Supplier must create and maintain pursuant to the MDR, as well as those which form part of its quality management system. Further details can be agreed separately.

## 14 Change management/contract amendments

### 14.1 Product Change Notifications (PCN) and Product Termination Notifications (PTN)

1. The Supplier shall direct Product Change Notifications (PCN) and Product Termination Notifications (PTN), as well as requests for special approvals, to the Customer via email: ptn.pcn@richard-wolf.com.

2. It is particularly incumbent upon the Supplier to submit a PCN/PTN or a request for special approval if it is considering changes affecting the following aspects:

   *(a) Product-related aspects:*

   - Specification
   - Safety
   - Function
   - Conformity
   - Performance/effectiveness
   - General availability
   - Product documentation

   *(b) Production-related aspects:*

   - Special processes (e.g., packaging and sterilization) used during production
   - Validated processes
   - Methods and procedures for quality assurance
   - Production environment
   - Changes to subcontractors, which have a significant impact on product quality and safety

   *(c) Other measures, which could affect product safety and performance*

3. Every PCN/PTN or request for special approval shall contain the following information:

   - Product name, type number, and material number
   - Precise timeline of the product change or termination
   - Qualification and reliability reports/proofs of verification and validation for the product or production process being changed
   - Contact details in the event of any questions

4. Further details can be specified separately.

## 14.2 Change process

### 14.2.1 Change (initiated by the Supplier)

1. Information about the PCN/PTN shall be provided immediately and the proposed timeline for implementation must take the legitimate economic interests of the Customer into account. If this is not the case, the timeline for implementing the PCN/PTN will either be modified appropriately or implementation will be rejected outright.

2. If the PCN relates to eliminating problems that affect safety, the Supplier and the Customer shall immediately initiate all the measures needed to rectify the problems.

3. If the PTN relates to a standard product termination, the Customer shall be given the opportunity to place a final purchase order.

4. After receiving the PCN/PTN or the request for special approval, the Customer shall communicate to the Supplier in writing whether the Supplier is to make amendments vis-à-vis the original purchase order and specify which amendments are to be made. The Supplier shall confirm receipt of the amended specifications in writing and ensure its technical documentation is modified accordingly, all according to the timeline it had previously agreed with the Customer.

5. The Supplier undertakes to make no changes to products or processes without prior written approval from the Customer. The Supplier shall work together with its subcontractors to draw up all the regulations necessary for fulfilling the obligations arising from this paragraph.

### 14.2.2 Change (initiated by the Customer)

1. Customer change requests are also initiated by submitting details of the planned change to the Supplier in writing. The Supplier shall confirm receipt of the request in writing and provide the Customer with the information specified in Item 14.1 without delay. In particular, the Supplier shall provide information about the cost of the change, its impact on the product price, and any qualifications, verifications, and validations necessitated by the change as soon as possible.

2. From then on, the procedure is as described in Item 13.2.1 et seq.

### 14.2.3 Organizational changes

The Supplier undertakes to inform the Customer of the following changes in writing:

a) Changes to the organization that affect ownership rights

b) Changes to the certification body, a change to the certification status, sanctions by authorities (e.g., FDA), etc.

c) Changes to the roles of economic operators (e.g., importers or authorized representatives) or their contact details

## 15 Audits (announced and unannounced)

### 15.1 Audit rights

1. The Supplier shall consent to its premises being audited and, if requested by the Customer, shall make arrangements to jointly audit a subcontractor. Audits shall take place on a previously agreed date.

2. Especially where critical products are concerned, the Supplier shall also consent to its premises being audited by the relevant notified body and authority for the Customer and shall make arrangements for said notified body and authority to audit a subcontractor. The relevant notified body and authority may also conduct these audits unannounced. In particular, the Supplier shall ensure that the requirements contained in Recommendation 2013/473/EU of the European Commission on unannounced audits, as defined in Item 7.2, are supported and implemented.

3. The Supplier shall disclose the records relating to the product or service in question to the auditors. Auditors shall also be entitled to take samples of products either from production or the warehouse to check they conform to the product specification.

4. The Customer shall be given the opportunity to attend every audit (whether announced or unannounced). Therefore, the Supplier undertakes to immediately inform the Customer about audits in writing. This information/notification shall be submitted in writing via email to ze@richard-wolf.com and fax to +49 7043 35-4133.

### 15.2 Organizational arrangements for audits

At least one qualified person shall be assigned to escort the auditors during regular office hours. The Supplier shall put appropriate internal regulations in place (e.g., stand-in regulations, internal training) to ensure that announced and unannounced audits, including those where samples are requested, can always be conducted properly.

### 15.3 Extent of access and inspection

1. The Supplier shall ensure that access is available to the production facility and that all the requisite documents and records, which the Supplier must create and maintain pursuant to this guideline, as well as those documents and records which form part of its quality management system, are available for inspection.

2. The Supplier shall ensure that the Customer's notified body and the responsible authority are contractually guaranteed to have access to subcontractors for auditing purposes.

### 15.4 Information about audit results

1. The Supplier undertakes to immediately inform the Customer in writing if a relevant authority or its notified body issues a written notification (e.g., warning letter, (certification) audit report)

requesting that it rectify major non-compliances identified during audits or requesting inspections which could jeopardize its certification status in relation to the Customer's products, or if the Supplier is requested to correct defects on products already delivered to the Customer.

2. The notification shall be forwarded to the following email addresses: ze@richard-wolf.com and auditmanagement@richard-wolf.com

3. Copies of reports on audits and inspections carried out at the Supplier shall be submitted to the Customer immediately on receipt if they affect the Customer's products.

### 15.5 Audits – dealing with non-compliances/corrective measures

1. If non-compliances are identified or corrective measures defined during an audit, the Supplier shall remedy or implement them promptly to ensure that no disadvantages arise for the Customer. In all cases, however, the deadlines specified by the notified body or authority are binding and shall be strictly adhered to.

2. Other than that, the Supplier shall ensure that:

   a) A detailed plan of action for correcting major and minor non-compliances is submitted no later than 14 days after the audit, which also specifies the relevant implementation deadline

   b) The corrective measures are implemented no later than 180 days after the audit, provided there is no justification for extending the deadline in this particular instance

   c) A written record of the implementation results is provided at the end of an agreed period, which contains verifiable proof that the non-compliances have been corrected

   d) At the Customer's request, the implementation results/progress of the implementation work shall be presented to the Customer on its site without delay, should the Customer consider this necessary and have reasonable grounds for it (e.g., insufficient written documentation relating to corrective measures or missed deadlines)

## 16 Quality data

### 16.1 Complaints and dispute management

1. Both parties shall establish and maintain an organized and documented complaints and dispute management system. The system shall be used to record quality findings from various product phases (e.g., development, production, maintenance, and information from the field) and to facilitate targeted evaluations of the data, which satisfy the criteria that apply to notifiable events.

2. The Customer shall record and document feedback on any quality problems that have occurred with the Supplier's products, before forwarding the information to the Supplier in writing; the Supplier shall then respond, before introducing and taking appropriate measures.

3. Conversely, the Supplier undertakes to notify the Customer of any quality problems that have occurred in full and without delay, as soon as the Supplier becomes aware of any potential deviations from specifications in the Customer's products. The Supplier also gives the

assurance that it will provide the insights gained to the Customer for the purposes of evaluating and appraising complaints and notifiable events.

4. Both parties give the assurance that they will exchange data requisite to the maintenance of the risk management system on a regular basis.

## 16.2 Notifiable events

1. The parties shall inform one another of any notifiable events immediately in writing. This also concerns products which are similar to those deemed notifiable.

2. The notification shall be forwarded to the following email address: QS-Trendanalysen@richard-wolf.com.

## 16.3 Trend analyses

1. The Supplier gives the assurance that it will keep defect statistics for all conducted tests and make the results available to the Customer. Conspicuous abnormalities (e.g., a rate of rejected products >3%) shall be reported immediately; otherwise, the information shall be provided at least once per year.

2. These statistics relate to the type of error and its location, as well as the associated testing decision (rework, scrap, downgrade, special approval). The details can be specified separately.

3. The notification shall be forwarded to the following email address: QS-Trendanalysen@richard-wolf.com.

## 16.4 Post-market surveillance plan

1. The MDR requires manufacturers of medical devices to create a post-market surveillance plan for their products (PMS plan reporting requirement relating to the safety of the medical device). If required and applicable, and requested by both parties, the Supplier and the Customer shall share post-market surveillance data for the products. Both parties shall support one another appropriately and to a reasonable extent.

2. If the Supplier has clinical data and application data for the product, which the Customer needs now or will need in future, the Supplier shall make this data available to the Customer in full and shall continue to collect and maintain it in future.

## 16.5 Corrective measures

1. If the Customer puts medical devices on the market, the Customer is also responsible for assessing and performing any corrective measures. The Supplier shall support the Customer in this and the parties shall agree on any corrective measures, including recalls, corrective work in the field, or safety notices.

2. If the Supplier is identified as being the case of corrective measures, the Supplier shall bear the costs of said corrective measures.

# 17 Liability insurance

1. The Supplier undertakes to take out and maintain liability insurance with worldwide coverage and an amount of cover appropriate to the products of at least €3 million per instance of

personal injury for each individual person, at least €5 million per instance of material damage, and at least €5 million for pecuniary loss. At the same time, the Supplier hereby assigns any claims arising from the liability insurance, including all ancillary rights, to the Customer. The Customer hereby accepts this assignment. If an assignment is not permissible in accordance with the insurance contract, the Supplier shall hereby instruct the insurer that any payments are only to be made to the Customer. Further claims on the part of the Customer shall remain unaffected by this. Upon request, the Supplier must demonstrate to the Customer that liability insurance has been taken out and is being maintained. The Supplier shall refrain from or cease any action that may jeopardize the insurance coverage.

2. If the Supplier does not adequately fulfill its obligations, the Customer shall be entitled, but not obligated, to take out liability insurance at the expense of the Supplier.

## 18 Confidentiality

The Supplier and the Customer agree that all information exchanged in relation to this guideline must be treated in confidence. The only exception to this rule is information that has to be shared with notified bodies and authorities in the context of monitoring and supervision by them.

## 19 Retention of documents and files

1. Even once the delivery relationship between the Supplier and the Customer is over, the Supplier shall retain all the requisite documents and records, which the Supplier must create and maintain pursuant to this guideline, as well as those which form part of its quality management system, for at least 15 years after the last time the products were delivered or placed on the market, and shall make them available to the Customer on request. For implantable products, this period shall be at least 15 years after the last product was placed on the market or at least the maximum intended residence time of the implant, whichever is longer.

   This includes in particular, but is not restricted to:

   - QM systems
   - Specifications
   - Retention of documents and quality records, traceability
   - Complaints management
   - Market surveillance
   - Liability insurance
   - Confidentiality

2. The Supplier shall only destroy the documents and files after the Customer has given its written consent. The Customer shall be given the opportunity to archive the Supplier's documents and files itself.

## 20 Final provisions

1. No amendments or additions to this guideline are binding upon either contracting party unless made in writing. This applies also to any waiver of the requirement for the written form.

2. The legal relationships between the Supplier and the Customer are governed by the law of the Federal Republic of Germany to the exclusion of the United Nations Convention on Contracts for the International Sale of Goods (CISG).
3. The exclusive legal venue for all disputes arising from the business relationship between the Supplier and the Customer shall be the registered office of the Customer. The Customer shall also be entitled to bring legal proceedings at the registered office of the Supplier as well as at any other permissible legal venue.
4. If certain provisions of this guideline are invalid, this shall not affect the validity of the other provisions nor the continued existence of the guideline. The invalid provisions shall be replaced by a new regulation that comes as close as possible to the economic intent of the invalid provisions. The same applies accordingly in the event of a loophole.
5. The rights and obligations arising from this guideline or parts thereof may not be assigned.
6. The parties undertake to also impose the obligations contained in this guideline on any legal successors they may have.

The Supplier hereby accepts and confirms the conditions of the quality guideline (P02DO011):

_____
Place, date

_____
Name of the Supplier/company stamp

_____
Legally binding signature

_____
Name of the signatory in block letters

_____
Position of the signatory