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QUALITY MANUAL

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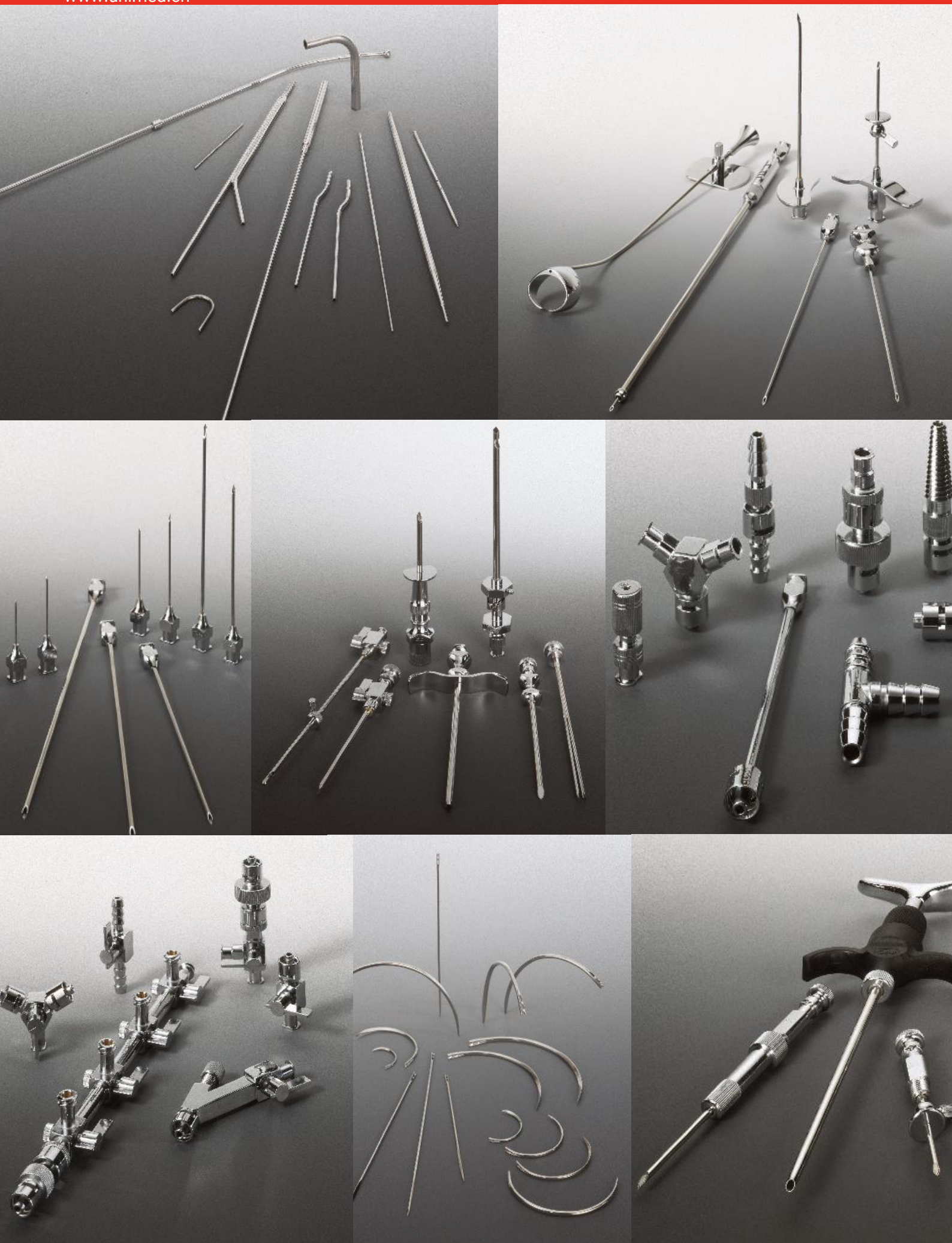

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0. PURPOSE

The purpose of the quality management system (QMS) of Unimed SA (UNIMED) is to describe the general organization of the company UNIMED in order to conduct the planned activities.

0.1 PRESENTATION OF THE COMPANY

In 1936, Pierre-Jean Guisan, the son of a doctor and a nephew of the famous Swiss Commander in Chief, General Guisan, commenced the manufacture of hypodermic needles on a modest scale. The company which he set up in the name of P.-J. Guisan S.A. manufactured articles for medical doctors and dentists. After various changes of ownership, the needle factory was taken over by Mr. Carl Schoenholzer in 1958 under the new name of Unimed SA.

The new company specialized increasingly in the manufacture of all types of medical needles and surgical needles. Its product range was extended to include veterinary needles as well as connectors and stopcocks for all sorts of applications for the flow of fluids.
The products manufactured are supplied in non-sterile packaging. Although clean in the normal sense of the term, the user must give products a final wash in a clean room and then pack and sterilize them appropriately in relation to the specific requirements of their use.

Originally the manufacturing program was sub-divided as follows, from a sales point of view:
- Medical needles (for injections, punctures, biopsies, etc.).
- Dental needles.
- Suturing needles.
- Veterinary needles.
- Connectors and stopcocks.
- The supply and custom manufacture of stainless steel tubing and wires from 0.1 mm to 10 mm in diameter.

Those products were not developed by Unimed SA, but were the result of researches done by various doctors and scientists, which acquired a certain notoriety in connection with the discovery of new therapeutic or diagnostic methods.

At the end of 2020 with the entry into force of the new European regulation (MDR) on medical devices, Unimed SA decided to stop the manufacturing and the selling of its own products to focus on its subcontracting activity.

Nowadays, the company employs more than 200 employees and exports to over 70 countries worldwide account for 80% of the company's turnover. Customers come from a variety of fields such as medicine, pharmaceutical research, analysis laboratories, dental medicine, veterinary medicine or also classical industry, food industry, watch manufacturing industry or even automobile industry to a lesser extent.

The essential of the company’s activity is based on the manufacture of articles to our customers' specifications. These articles are manufactured on demand on the basis of specifications, which may vary in detail, supplied by the customer, with or without the prior approval of samples.
The remainder of the manufacturing program is composed of standard articles such as industrial and veterinary needles as well as adapters and stopcocks for industrial/veterinary use as illustrated in the corresponding catalogues.

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These have not been developed by Unimed SA, but are the fruit of research by various doctors and scientists who have achieved certain renown in relation to the discovery of a new therapeutic or diagnostic method.

In 2022, the company moves its headquarters and production to a new facility on Avenue du Tir-Fédéral, in Ecublens VD.

0.2 STRUCTURE OF THE QUALITY MANAGEMENT SYSTEM

The QMS structure is principally based on the standard ISO 13485 and designed on 2 management basics principles:
- Systemic approach.
- Organization by activities.

To define the QMS and ensure its adequacy with its activities, UNIMED takes into consideration the product lifecycle and the realization flow from the initial quote to the expedition of the finished product.

The organization by activities of UNIMED QMS is based on 2 elements documented in its organizational procedures:
- Organisational processes.
- Organisational good practices.

The QMS describes its organizational processes and good practices while ensuring the systemic coherence through a global mapping representing activities of the company (4.1.2).

The organizational processes and good practices are defined in a manner to ensure the quality policy for each type of products in function of their particular requirements.

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1. SCOPE

1.1 GENERAL

The *QUALITY MANUAL* is applicable for all the company UNIMED for their owned products and products manufactured for customers.

1.2 NON-APPLICABLE

The subjects below are not applicable for the QMS and manufactured products by UNIMED.

Subject	ISO 13485	ISO 9001	21 CFR Part 820	Non-applicable rational
Design and development	7.3	8.3	820.30	UNIMED only contract manufactures components on defined requirements by customers and sell their own existing non-medical products (see 4.1.2). UNIMD non-medical products have a defined frozen design.
Installation activities	7.5.3	8.5.5	820.170	UNIMED does not manufacture products that require installation activities or post-delivery activities.
Servicing activities	7.5.4	--	820.200	UNIMED does not provide servicing activities associated to their products.
Sterile medical device	7.5.5 7.5.7	--	--	UNIMED does not manage any sterilisation process
Active medical device	--	--	--	UNIMED does not manufacture active medical device.

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2. NORMATIVE REFERENCES

The structure and operations of the QMS is based on the current versions of the following standards.

- ISO 13485 Medical devices - Quality management system - Requirements for regulatory purposes.
- ISO 9001 Quality management system - Requirements.
- 21 CFR Part 820 Quality System Requirement (QSR).

The applicable version of these standards above is documented in the list *APPLICABLE STANDARDS*.

The list *APPLICABLE STANDARDS* of all technical and organizational standards is maintained up-to-date is regularly reviewed to ensure being compliant to the current version.

The follow-up of the standards applied by UNIMED is continually made per procedure *MARKET SURVEILLANCE*. A documented review is yearly provided for the annual management review per procedure *MANAGEMENT REVIEW*.

3. TERMS AND DEFINITIONS

The instruction *TERMS & ABBREVIATIONS* defines the specific terms used within UNIMED as part of its organizational processes and organizational good practices.

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4. QUALITY MANAGEMENT SYSTEM

4.1 MANAGEMENT SYSTEM

4.1.1 GENERAL

UNIMED QMS is:
- Structured based on the standard ISO 13485. It also integrates different management systems through its organizational processes and good organizational practices.
- Documented in French with the exception of a copy of the quality manual in English.
- Some specific documents can be in English based on their use.

Each management system integrated into UNIMED QMS is described in a specific quality plan (PAQ) demonstrating its integration.

Management system	PAQ #	Standard
Risk management system (SMR)	SMR.PAQ	ISO 14971 / ISO 31000
Post-Market Surveillance (PMS)	PMS.PAQ	93/42/CEE / 21 CFR Part 803
Environment management system (SME)	SME.PAQ	814.01
Health and safety management system (SMSST)	SMSST.PAQ	822.11 / 832.20

4.1.2 ORGANIZATION ACTIVITIES

The UNIMED activities are documented on the ISO 13485 and 9001 certificates as follows:

Contract manufacturer of needles and customized micromechanical components made of metals for medical devices.

Manufacture of veterinary needles, industrial needles and micromechanical components made of metals. Contract manufacturer of customized needles and micromechanical components made of metals.

UNIMED is essentially a manufacturer or contract manufacturer of medical devices based on stainless steel tubes. UNIMED does not develop new medical devices in its own name.

Product	Unimed Role	Description	Applicable standard
UNIMED product	Manufacturer	Catalogue products developed by UNIMED in the past and still manufactured. They are sold to different importers, distributors and final users. - Veterinary needles - Industrial needles - Mechanical components for industrial use	ISO 9001
Customized product	Contract manufacturer	Products manufactured exclusively per customer specific requirements. The responsibility of design and function of the product is owned by the customer. It is also applicable for the sale of tubes and barres.	ISO 9001 ISO 13485 21 CFR Part 820

All these activities are realized while respecting the *CODE OF CONDUCT* of UNIMED.

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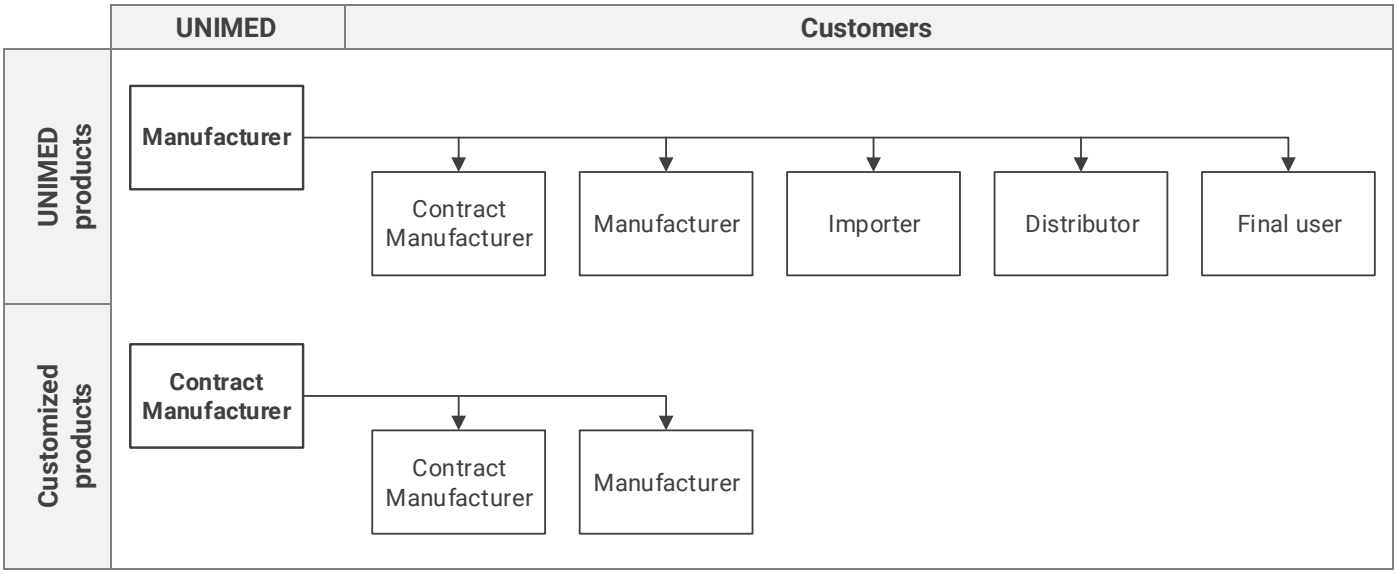
4.1.3 ORGANIZATION

The table below describes organizations and roles in the products supply chain.

Role	Description	Organization	
		UNIMED	Customers
Manufacturer	All organizations (natural or legal person) responsible for the design and production of a product placed on the market. UNIMED as a manufacturer of products for veterinary and industrial uses supplies importers, distributors and final users.	✓	✓
Contract manufacturer	All organizations (natural or legal person) responsible for the production of products or product components for a customer being the manufacturer of the concerned product, or a contract manufacturer.	✓	✓
Importer	All organizations (natural or legal person) which import UNIMED products in an authorized country or jurisdiction by UNIMED. An importer can also distribute UNIMED products.		✓
Distributor	All organizations (natural or legal person) which distribute an UNIMED products to others distributors or final users.		✓
Final user	All organization (natural or legal person) using the manufactured product at its final purpose. A final user can also be an importer.		✓

The table below represents the 2 supply chain flows in functions of the nature of the manufactured products and the type of organization.



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UNIMED does no longer place medical devices on the market on its name but must cover products distributed during their lifetime. Consequently, the role of authorized representative remains active as long as the coverage of these products is necessary.

The table below describes the organizations and roles in the representation by reporting to different regulatory and legal requirements.

Role	Description	Market	Organization
Authorized representative	All organizations (natural or legal person) which represent UNIMED in a country or jurisdiction for specific activities responding to legal obligations. *Complete applicable description per ISO 13485, section 3.*	EU	UNIMED
		USA *(USDA)*	FARRELL CONTRACT ENGINEEING, LLC 750 Mainstreet, Unit 328 Hopkins, Minnesota, 55343 USA

UNIMED context and interested parties are described in the instruction *CONTEXTE*.

4.1.4 PROCESSES, GOOD PRACTICES AND THEIR INTERACTIONS

UNIMED has defined 4 principal areas to realize his activities. For each area is designed a director and//or managers. They are responsible with the organisational processes and organisational good practices owners to reach the planned objectives in relation with the allocated resources

The 4 areas, and their respective responsible, are:

- Management — CEO
  COO
- Commercial — Commercial Director (Com. Dir.)
- Technique — Production Director (Prod. Dir.)
  Purchasing and Maintenance Manager (P&M Mgr.)
  R&D Manager (R&D Mgr.)
- Quality — Quality Director (QA Dir.)

Each area contains organisational processes and organisational good practices with owners that are not necessarily the directors or managers of the respective area (see section 6.2.1 for the functional organizational chart).

Each area is monitored and analysed by their respective manager or director who measure their obtained performances and compare them the planned ones (8.2). Improvement actions are conducted to continually ensure obtaining planned results and efficiency of processes

Quality and regulatory requirements applicable to UNIMED QMS (2.) are documented through the procedures documenting organisational procedures and good practices. Their distribution is documented through the list *QMS PROCEDURES VS QUALITY STANDARDS*.

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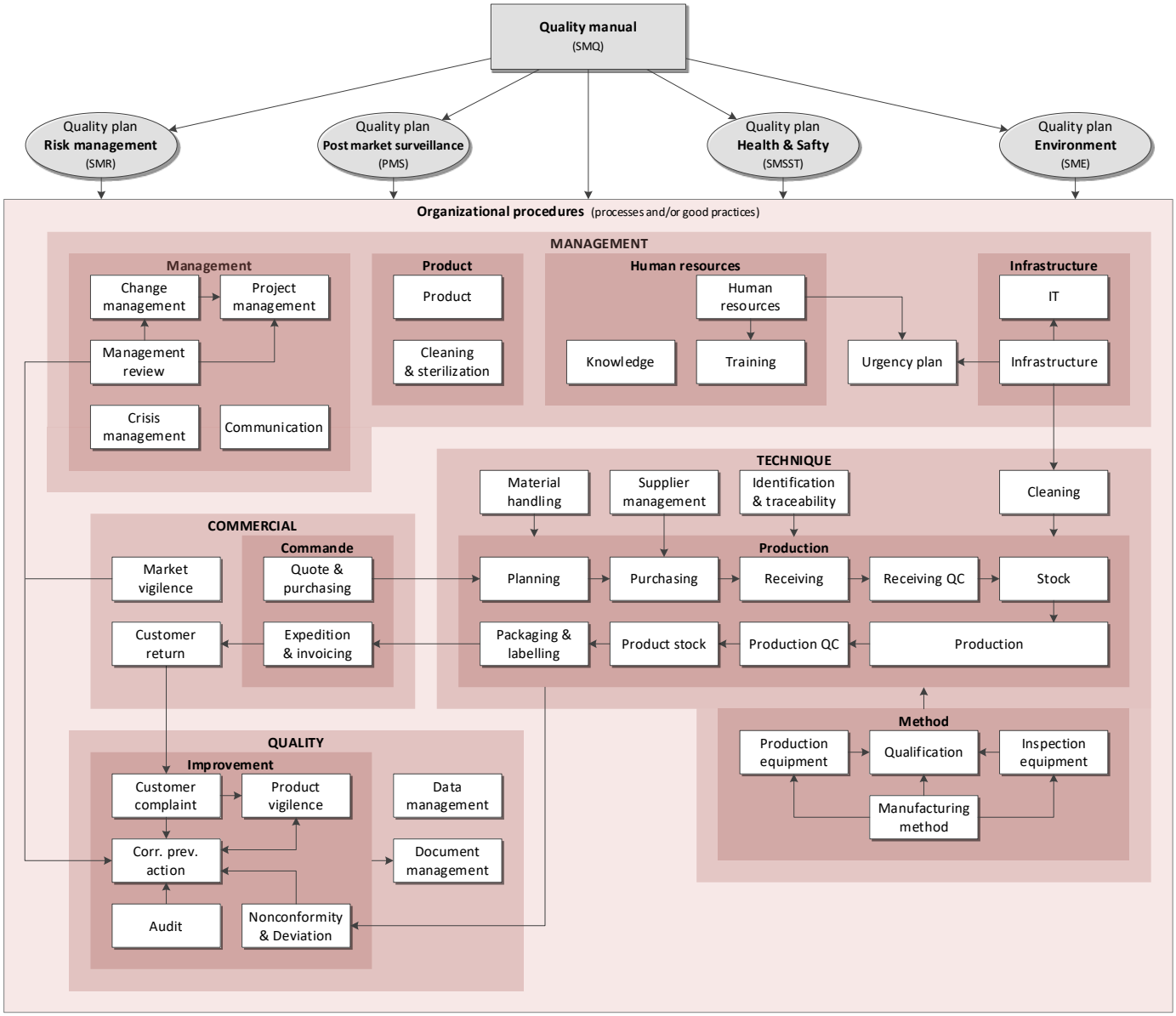
The mapping represents the global QMS and its organisational processes and organisational good practices with their principles interactions.



All organisational processes and all organisational good practices are supported by 41 organizational procedures (PO) listed in annex #2. Owners and people concerned by these procedures are documented in the list *QMS DOCUMENT MATRIX*.

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4.1.5 CHANGE MANAGEMENT

The management of changes covers all aspects of the QMS and links with external parties (customers, suppliers, certification body, …).

An information sheet about change management is available on UNIMED internet site for customers.

The management of changes is realized through a process described in the procedure *CHANGE MANAGEMENT*.

4.1.6 OUTSOURCED PROCESSES

Outsourced processes are managed through their appropriate suppliers. All suppliers are managed through a data base with the provided products and/or services.

The approved supplier list *SUPPLIER* list all critical and non-critical suppliers requiring an approval per the supplier management procedure *SUPPLIER*.

4.1.7 QMS SOFTWARE VALIDATION

All software used by UNIMED are listed in a database with assessment determining if they need to be validated or not.

The appropriate assessments and validation are conducted per instruction *SOFTWARE VALIDATION*.

4.2 DOCUMENTS MANAGEMENTS

4.2.1 GENERAL

The necessary documentation (data and documents) to the QMS operations contains the present *QUALITY MANUAL* (4.3.2) including the quality policy (annex #1), procedures (annex #2), instructions, forms and others.

The documentation also contains records and all required documents by the QMS or to demonstrate conformance to applicable standards and regulations.

Documentation also includes technical files for EC conformance of UNIMED medical devices as required per the European directives.

4.2.2 QUALITY MANUAL

The *QUALITY MANUAL* defines the QMS structure and the UNIMED organization. It is the head of the document structure.

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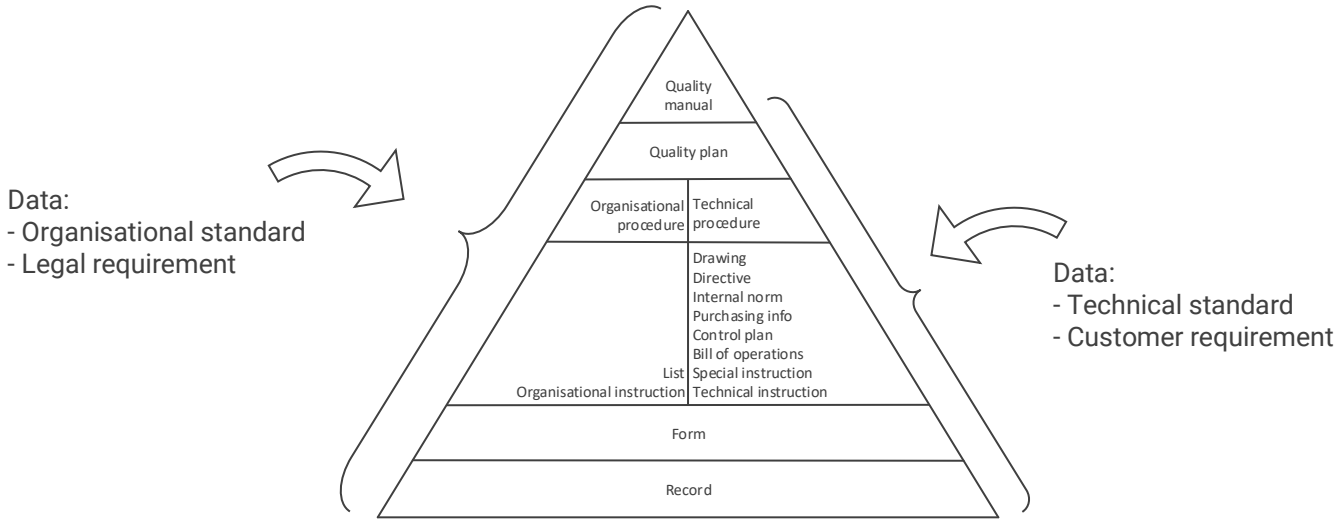
The QMS documentation is structured by the following documentation pyramid.



Each document is managed and identified per rules defined in the procedure *DOCUMENT MANAGEMENT*.

4.2.3 CONTROL OF DOCUMENTS

Only the electronic version of a document is valid. All paper versions are valid when printed. Its user is responsible to verify that the used version is up-to-date.

For the distribution of certain documents under control in area that does not have access to a computer, the distribution system is described in procedure *DOCUMENT MANAGEMENT*.

The *QUALITY MANUAL* is the only document that can be freely distributed to customers. For all others documents, an approval is required and the document can be adapted before being distributed or partially distributed.

4.2.4 CONTROL OF RECORDS

Records described in the procedure *DOCUMENT MANAGEMENT* are identified and managed through rules defined in the procedures generating these records.

The archive of records is a minimum of medical device lifetime but no less than 20 years or less than regulatory requirements.

All records are listed in the list *RECORDS*.

The importance of records is described in the procedure *DATA MANAGEMENT*.

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5. MANAGEMENT RESPONSIBILITY

5.1 TOP MANAGEMENT LEADERSHIP AND COMMITMENT

The top management is committed to:
- Taking accountability for the effectiveness of the QMS and its integration in the processes and good practices of UNIMED.
- Ensure that the QMS achieves its intended results.
- Communicate through the organization the importance of satisfying customer requirements and regulatory and legal requirements and promote improvement.
- Establish the quality policy documented in the quality manual *QUALITY MANUAL*.
- Establish quality objectives, documented in the list *INDICATOR*.
- Conduct annual management review per procedure *MANAGEMENT REVIEW*.
- Ensure the availability of resources (human, material, infrastructure and financial).
- Support other management roles to demonstrate their leadership as it applies to their areas of responsibility, and support employees to contribute to the effectiveness of the QMS.

The top management is represented by the C.O.O.

Projects of UNIMED are regularly followed by the management and concerned project leaders per procedure *PROJECT*.

In case of a crisis impacting the company, the management takes in charge all necessary activities and decisions to take based on the recommendations of the procedure *CRISIS MANAGEMENT*.

5.2 CUSTOMER FOCUS

The global notion of "customer" regroups several categories (4.1.3):
- Practitioner (final user).
- Supply chain (importer or distributor).
- Legal manufacturer (manufacturer).

Each of these categories has its own needs and expectations:
- For the patient, we take into account the product reliability ensuring that customer requirements are determined and satisfied.
- For the supply chain, availability of UNIMED industrial products, traceability, products quality and marketing support.
- For the legal manufacturer, respect of their requirements for the production of costumed products.

Any positive or negative pertinent feedback from these categories is diligently treated and recorded for potential improvement per procedure *MARKET SURVEILLANCE*.

All return products form a customer due to cancelling or modification of a purchase order or for investigation is treated per procedure *CUSTOMER RETURN*.

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5.3 QUALITY POLICY

The quality policy provides the company context and a framework for establishing objectives. It is documented in the annex #1 under the responsibility of the top management.

Its adequacy with the company strategy is re-examining at each annual management review per procedure *MANAGEMENT REVIEW*.

5.4 PLANNING

5.4.1 QUALITY OBJECTIVES

The general objectives of UNIMED are documented in the quality policy.

Quality objectives are review at each annual management review per procedure *MANAGEMENT REVIEW*. They are followed through appropriate performance indicators documented in the list *INDICATOR*.

Performance indicators are communicated to concerned people. If needed, they can delegate to collaborators.

5.4.2 QMS PLANNING

QMS planning is ensured trough:
- Setting and follow-up of QMS organisational procedures.
- The deployment of objectives relating to different areas, organizational processes and good organizational practices.
- Monitoring of legal and regulatory framework specific to products.

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 RESPONSIBILITY AND AUTHORITY

The general organization of UNIMED is set by the top management. It is described and documented in the 2 following elements:
- Mapping of organizational processes and good organizational practices (4.1).
- Functional organigram (6.2.1).

The links between these 2 elements are defined in the list *QMS DOCUMENT MATRIX* defining which procedure is applicable for which function. The matrix also defines each procedure owner, so responsible for its content.

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5.5.2 GENERAL MANAGEMENT REPRESENTATIVE FOR COMPANY MANAGEMENT

The CEO has appointed a COO for the specific following tasks:
- Ensure the daily management of the company and coordination between departments.
- Guide directors and managers on the tasks to be carried out and the directions to take.
- Report on the general functioning of the company and any need for improvement.

5.5.3 MANAGEMENT REPRESENTATIVE FOR QUALITY

The CEO has appointed a QA Dir. for the specific following tasks:
- Ensure that the QMS is establish, implemented and maintain.
- Reporting the QMS operations and improvement needs.
- Follow and integrate the legal and regulatory framework specific to products and/or customers' demands.
- Being the person responsible for regulatory compliance.

5.5.4 MANAGEMENT REPRESENTATIVE FOR HEALTH AND SAFETY

The CEO has appointed a Safety Officer for the specific following tasks:
- Ensure that the HSMS is establish, implemented and maintain.
- Reporting the HMMS operations and improvement needs.
- Follow and integrate the legal framework.
- Being the person responsible for legal compliance.

5.5.5 COMMUNICATION

UNIMED organization is opened between hierarchical levels and promotes an open, direct and spontaneous communication.

Different ways are used to ensure an efficient communication:
- Dissemination of *QUALITY MANUAL* and procedures in workshops and on the IT network.
- Communication by email.
- Verbal and spontaneous communication between involved people.
- Working meeting (written if necessary).
- Annual evaluation interview.
- A year-end speech is for all staff by the top management.

If necessary, a specific communication can be established by the top management based on a specific event.

The organization's standard methods and media of communication are documented in the procedure *COMMUNICATION*.

The urgency plan describes some specific crisis communications per procedure *URGENCY PLAN*.

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5.7 MANAGEMENT REVIEW

5.7.1 GENERAL

Once a year, the management conducts a review of the QMS operations as documented per procedure *MANAGEMENT REVIEW*.

Directors and managers prepare a report for each area based on inputs (5.6.2). Conclusions and decisions will complete the final management review report in accordance with outputs (5.6.3).

5.7.2 REVIEW INPUTS

- Performance indicators and analyses by their owners (per list *INDICATOR*).
- Results of customers, notified body and internal audits.
- Customers and market feedbacks.
- Processes operations and products conformities and monitoring.
- Status of corrective and preventives actions.
- Actions from previous review.
- Organisation or regulatory requirements changes that could affect the systems.
- Improvement recommendations.
- New or revised regulatory requirements.

5.7.3 REVIEW OUTPUTS

- Improvement needed to maintain the suitability, adequacy, and effectiveness of the systems.
- Improvement of product related to customers and regulatory requirements.
- Corrective and preventives actions on processes and/or products identified during the review.
- Resources needs.

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6. RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

The top management provides the necessary resources (material, human and financial) based on the available capabilities to support the company's activities, maintain the effectiveness of the QMS and meet regulatory and customer requirements.

Resources are regularly reviewed and evaluated based on customer requests, release of regulatory requirement and during the annual management review per procedure *MANAGEMENT REVIEW*.

6.2 HUMAN RESOURCES

6.2.1 GENERAL

Employees are hired for identified needs based on their education, competencies and professional experience per procedure *HUMAN RESOURCES*.

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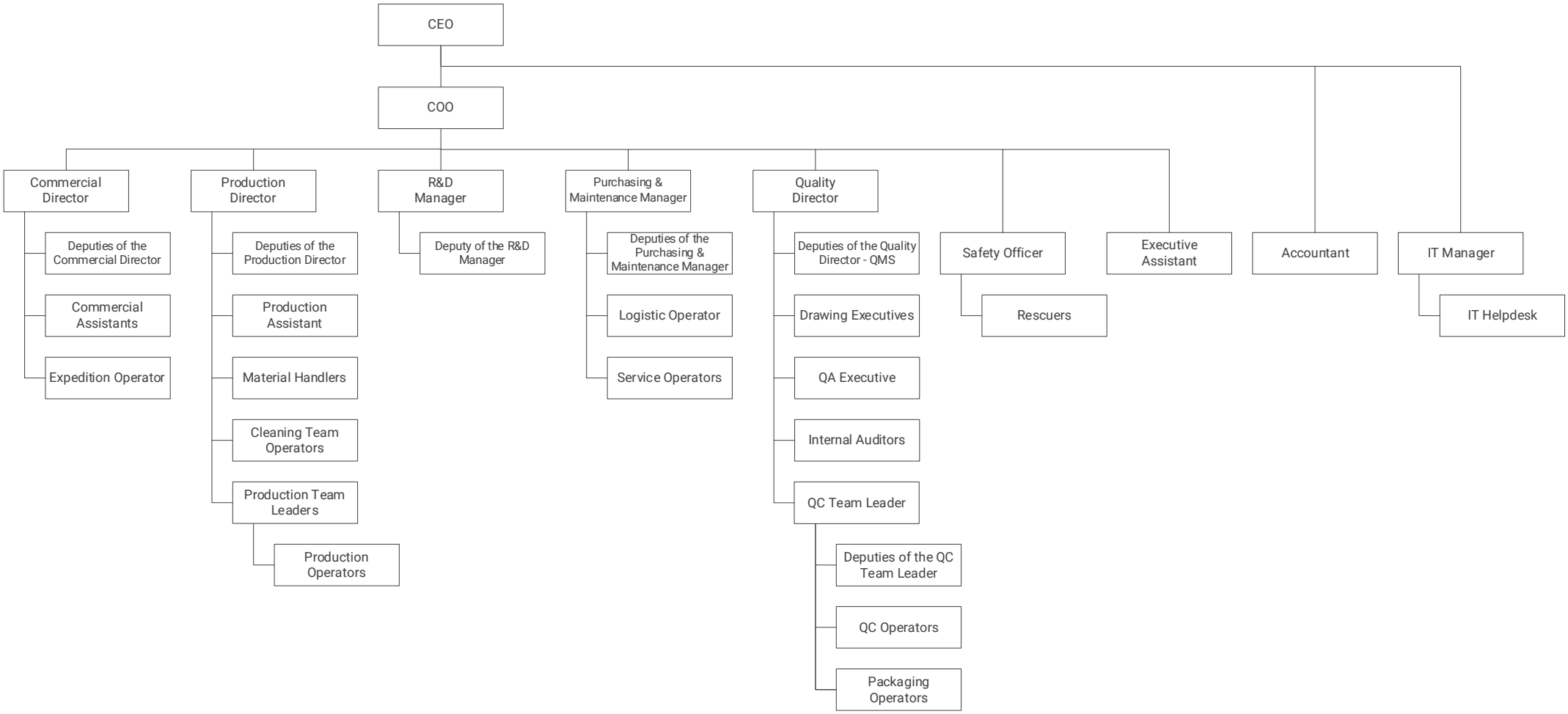
The top management defines UNIMED organization described in the following functional organizational chart.



For each function a job description describes the appropriate tasks, competencies and authorities.

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When needed UNIMED may use external consultants for specific competences missing internally.

An annual evaluation of each employee is conducted and a feedback is provided by its direct supervisor of his performance during the evaluated period per procedure *HUMAN RESOURCES*.

2 company regulations are distributed to every new employee based on their function.

In case of employee accident, accident details are recorded and, for professional ones, corrective actions can be taken, per procedure *URGENCY PLAN*.

6.2.2 COMPETENCES AND TRAINING

When hiring, all new employees receive introduction training adapted to their activities and concerning organizational aspects, quality and safety and on-the-job activities by his direct supervisor per procedure *HUMAN RESOURCES*.

Training needs are identified either during the hiring, punctual needs or annual evaluation interview.

Training efficiency is verified by the supervisor and documented during the next annual evaluation interview.

Copies of training certificates and others justifications are kept in employee file.

All these activities are described in the procedure *TRAINING*.

6.3 INFRASTRUCTURE

Production areas are identified as is at each entrance. They are accessible only to authorized employees. External visitors must be accompanied by an authorized internal employee, or trained for proper behaviour in these areas.

The management of specific subjects linked to infrastructure is documented in procedure *INFRASTRUCTURE*. This procedure include normal and special waste management

In case of building evacuation, an evacuation instruction of production and office areas is documented in the procedure *URGENCY PLAN*.

Information technology resources (hardware and software) are directly managed by the Man. Dir. per procedure *INFORMATION TECHNOLOGY*.

Infrastructures are regularly reviewed and evaluated based on customer requests and during the annual management review *MANAGEMENT REVIEW*.

Production equipment (per *PRODUCTION EQUIPMENT*) and inspection equipment (per *INSPECTION EQUIPMENT*) resources are determined by the responsible of each department and, if necessary, approved by the general management.

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6.4 WORK ENVIRONMENT AND CONTAMINATION CONTROL

6.4.1 WORK ENVIRONMENT

No cleanliness or particular protection requirement is necessary for UNIMED work environment.

All production areas are non-smoking areas and animals are not allowed.

The Prod. Dir. ensures that all production employees have been informed on procedures to follow-up, behaviours to adopt and understanding the warnings.

Work environments are regularly reviewed and evaluated based on customer requests and during the annual management review *MANAGEMENT REVIEW*.

6.4.2 CONTAMINATION CONTROL

All work environments are regularly cleaned by internal employees and an external company per procedure *CLEANING*.

6.5 KNOWLEDGE

UNIMED manages its necessary explicit and tacit knowledges through the following elements:
- QMS organisational and technical documents
- Employee experience and competences acquires internally or through their education.
- Relevant data from outside (literature, training, external documentation, …).
- Experience acquired within UNIMED recorded through various reports.

Explicit knowledge is available for the entire company and tacit knowledge is transferred by training or transmission.

Knowledge management is documented through the procedure *KNOWLEDGE*.

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7. PRODUCT REALISATION

UNIMED manufactures 2 types of products for its customers:
- UNIMED products for industrial use, under its own name
- Customized products, per established customer requirements

7.1 PLANNING OF PRODUCT REALISATION

For each product to realize, UNIMED take into accounts requirements from different processes, from products and from customer in order to plan its realization.

This planning includes:
- Manufacturing and product requirements (when applicable):
  - Product drawing.
  - Manufacturing process technical specification.
  - Components and sub-assembly drawings.
  - Bill of operations.
  - Inspection plan.
  - Special instruction.
- Documented requirements from risks.
- Necessary requirements for records in order to bring evidence that realization processes satisfies QMS requirements.

The procedure *PLANNING* describes all activities to put a product in production, whether new or a new version or a current version.

7.2 CUSTOMER-RELATED PROCESSES

7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO PRODUCT

For UNIMED products, specifications are established in the technical file (4.2.3) and applied as is. No modification of these products will be made for customers.

For customized products per customer requirements, specifications are established by customer under the form of a technical drawing and sometimes a quality agreement (or equivalent).

In that case, parties' responsibilities are shared like that:
- For a realization request of a new product, UNIMED takes into account customer requirements and manufacturing processes requirements.
- For demand of existing products, UNIMED works on written orders referencing product numbers. If the customer request data are not enough, a contact can be taken with the customer to require more information.

7.2.2 REVIEW OF REQUIREMENTS RELATED TO PRODUCT

For every quote request or purchase order of products, UNIMED verifies that product requirements are defined, documented and achievable.

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If the product requirements differ from standards, UNIMED verifies that these requirements can be achieved and then inform the customer before confirming the purchase order.

For any product specifications or requirements changes, UNIMED ensure that the concerned employees are informed of changes and that all corresponding documents have been updated.

All these activities are described in the procedure *QUOTE & PURCHASING*.

7.2.3 COMMUNICATION

UNIMED product descriptions are available for customers. UNIMED product catalogues and the internet site provide the necessary information.

Contracts with customers are integrated in customer files, if applicable and accepted.

Information feedbacks from customers are treated by the commercial area through the procedure *MARKET SURVEILLANCE*.

All customer complaints are treated and recorded per procedure *CUSTOMER COMPLAINT*. In case of any risk for users and other customers, information is published in the shortest possible time.

7.3 PURCHASING

7.3.1 PURCHASING PROCESS

All purchasing activities for all materials are treated as described in the procedure *PURCHASING*.

The purchasing or raw materials, components, sub-contracting activities linked to products, the supplier must be homologated in order to place a purchase order per procedure *SUPPLIER*.

7.3.2 PURCHASING INFORMATION

The following documents can serve as specifications including purchasing requirements for a supplier:
- Purchase order.
- Purchase data.
- Product drawing.
- Component or sub-assembly drawing.

The homologation of the supplier is important information documented in the database managing suppliers and purchase orders.

7.3.3 VERIFICATION OF PURCHASED PRODUCT

Different levels of receiving inspection are conducted depending on materials:
- The accuracy of supplier delivery note in relation to the identification of the goods and the purchase order.
- The presence and the conformity of attestation and other certificates requested.
- The functionality or features of goods, from the purchase specification.

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The supplier delivery note is approved when all necessary inspection have been conducted.

All received materials are inspected per procedures *RECEIVING* and *INCOMING QUALITY CONTROL*.

In case of non-conformity, purchased good is identified, segregate and treated per procedure *NON-CONFORMITY & DEVIATION*.

7.4 PRODUCTION

7.4.1 CONTROL OF PRODUCTION

General requirements

Production is organized into production teams, either for the manufacture of finished products or for the subcontracting of specific technologies, which are responsible for applying a number of assigned technical processes.

Depending on the need technologies, these production teams are called to subcontract to one or the other, the realization of sub-assemblies or the execution of a defined operation, as described in the procedure *PRODUCTION*.

At the end of the production process, the work order informs on the quantity effectively produced, the orders of sub-contracted work, the orders for rework and the final approved quantity for distribution.

Expedition and invoicing activities are conducted on conform products coming out from final quality control per procedure *EXPEDITION & INVOICING*.

Development and commissioning of a new manufacturing process or a modification of an existing manufacturing process is conducted per procedure *METHODS*.

Specific requirements

All products made by UNIMED are delivered non-sterile to customers. A final washing is conducted before expedition ensuring a cosmetic cleanliness that does not replace the final packaging and sterilization that must be performed before use. Sterilization remains the sole responsibility of the users.

For customer products, the customer is responsible for determining a final cleaning and ensuring the sterility of the product relative to the delivered product washed and packed out of the workshop.

7.4.2 CLEANLINESS OF PRODUCT

All products manufactured by UNIMED are washed so as to be delivered clean. This washing is intended to remove all residue of production but is not applicable as a final cleaning before a potential sterile packaging.

In the case of the UNIMED products for medical use (not produced and put on the market any more since end of October 2020 but still on the market), a disinfection and sterilization is necessary before their use by the final user per procedure *CLEANING & STERILIZATION*.

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This procedure is available on the company internet site (*www.unimed.ch*) in 3 languages: English, French and German.

7.4.3 QUALIFICATION OF PROCESSES FOR PRODUCTION

Process qualification includes the qualification of the 4 following elements:
- Installation (including production equipment and inspection equipment).
- Test method.
- Manufacturing process.
- Product.

Qualification of a new manufacturing process or a modification of an existing manufacturing process is conducted per procedure *METHODS*.

Different qualification approaches can be carried out depending on the needs of customers. These approaches are presented and available to customers on an information sheet on UNIMED internet site.

All qualification methods and their application rules are managed through the procedure *QUALIFICATION*.

7.4.4 IDENTIFICATION AND TRACEABILITY

Identification

All components and sub-assemblies used in the composition of a product are identified by a lot number.

Nonconforming products, components or sub-assemblies are identified as such by a label or the work order to prevent any risk of mixing.

The procedure *IDENTIFICATION & TRACEABILITY* described the used rules.

Traceability

Traceability is ensured by lot of material, components or individually carried reported on the work order of the product.

The product work order is reported on the customer purchase order ensuring traceability to the customer.

The procedure *IDENTIFICATION & TRACEABILITY* described the used rules.

Identification of the status

Non-conformity of a lot of component, sub-assembly or product is identified by a red non-conforming label in a specific container.

Nonconforming lots are not identified for a particular status.

If a lot is manufactured only for test, the lot is identified by its specific execution order documenting its purpose.

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7.4.5 CUSTOMER PROPERTY

Customer property consists of the following elements:
- Raw material or component owned by the customer (see the procedure *QUOTE & PURCHASING*).
- Measurement equipment owned by the customer (see the procedure *INSPECTION EQUIPMENT*).

Any deterioration of material owned by a customer is communicated to them to determine the action to put in place.

According to the source of the deterioration, the product will be considered as non-conforming and will be identified and treated per procedure *NON-CONFORMITY & DEVIATION*.

7.4.6 PRODUCT PRESERVATION

All components used to manufacture products are stored and managed accordingly. All stock movements of products are recorded.

Inventories of components or sub-assemblies are identified and managed specifically depending on the nature of the article per procedure *RECEIVING AND IN-PROCESS STOCK*.

A stock of manufactured products ready to be packaged and shipped is separately managed according to the procedure *PRODUCT STOCK*.

When handling articles, several good handling practices are taken into account and various containers can be used depending on the size, care and cleanliness required per procedure *MATERIAL HANDLING*.

The finished products are properly packaged and identified according to the procedure *PACKAGING & LABELLING*.

7.5 CONTROL OF MONITORING AND MEASURING EQUIPMENT

Monitoring and measurement equipment are managed and where applicable, regularly calibrated according to the procedure *INSPECTION EQUIPMENT*.

For most of monitoring and measurement equipment, an instruction is established that defines the method of verification and calibration, with the required periodicity.

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8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

In order, firstly, to demonstrate compliance of products and QMS and, secondly, to ensure its effectiveness, UNIMED collects and analyses different information.

This information can provide form:
- Customers.
- Market.
- Areas.
- Internal organisational processes.

Non-conformities are treated in order to avoid recurrence. Corrective and preventive actions are taken I the purpose of improving per procedure *CORRECTIVE & PREVENTIVE ACTION*.

The conformity of the QMS is verified through internal audit, customer audits, notified body certification/surveillance audit and national competent authority audit.

8.2 MONITORING AND MEASUREMENT

8.2.1 FEEDBACK

All information form a commercial or compliance source to UNIMED is treated through the procedure *MARKET SURVEILLANCE*.

According to the information criticality of the nature of the reported problem, the information is going to be kept or not. If the information is analysed as critical, the information will be treated either through a complaint per procedure *CUSTOMER COMPLAINT* or either through a preventive or corrective action per procedure *CORRECTIVE & PREVENTIVE ACTION*.

8.2.2 COMPLAINT HANDLING

Each customer complaint linked to deliver is recorded and treated per procedure *CUSTOMER COMPLAINT*.

The complaint is analysed and corrections a brought to the concerned products. Then, it is determined if a corrective action (ACP) is necessary based on the gravity of the event per procedure *CORRECTIVE & PREVENTIVE ACTION*.

8.2.3 INTERNAL AUDIT

Internal audit is a tool alloying to verify the conformity of the QMS and to identify potential improvements of organisational processes and good organisational practices per procedure *AUDIT*.

An audit planning is established and approved during the management review. It takes into account the status and the importance of processes and good practices.

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Internal auditors must justify a training to perform audits. An auditor is not allowed to audit its own work. In addition, the auditor must demonstrate impartiality and objectivity.
Audit results are recorded in an annual audit report.

All corrective actions issued from an internal audit are treated per procedure *CORRECTIVE & PREVENTIVE ACTION*.

A deadline for the resolution of a corrective action is defined between the auditor and the responsible of the audited sector (and/or his area director).

8.2.4 MONITORING AND MEASUREMENT OF PROCESSES

The ability of a process to achieve planned results is verified through various indicators, defined in the list *INDICATOR*.

They are the responsibility of each area director or manager and reviewed at least once a year during the management review through the procedure *MANAGEMENT REVIEW*.

These indicators can be linked to defined objectives or to QMS processes drifts or the realization of products. When results are not achieved, corrective actions can be taken.

8.2.5 MONITORING AND MEASUREMENT OF PRODUCT

The manufacturing file defines when quality inspections are necessary to verify the conformity of manufactured products.

Records of inspections (control reports) and production (work, execution and rework orders) are kept to demonstrate the conformity or manufactured products. These records show, in particular, who released the product for its use.

A production self-inspection or a quality inspection are often realized during the production to ensure the compliance of certain elements of a product that can no longer be inspected when the product is finished per procedure *PRODUCTION QUALITY CONTROL*.

A final quality inspection is conducted on all products manufactured by UNIMED before being shipped to customers per procedure *PRODUCTION QUALITY CONTROL*.

Non-conform products are treated per procedure *NON-CONFORMITY & DEVIATION*.

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8.3 CONTROL OF NONCONFORMING PRODUCT

8.3.1 GENERAL

All non-conform products are identified and separated from conform products for treatment per procedure *NON-CONFORMITY & DEVIATION*.

If the product can be put in conformity to the technical specifications, rework is conducted and indicated on a rework order per procedure *PRODUCTION*.

If the product can not be put in conformity to the technical specifications, a deviation can be requested from customer to accept the product as is per procedure *NON-CONFORMITY & DEVIATION*. If the customer refuses the deviation, the product will be destroyed.

8.3.2 ACTIONS IN RESPONSE TO NONCONFORMING PRODUCT BEFORE DELIVERY

If a non-conforming product is discovered before delivery, the product will be disposed by one of the following methods described below:

- 100% sort of the incriminated lot of products.
- Rework of the incriminated lot of products.
- Replacement of the incriminated lot of products.
- Derogation request of non-conforming products from the customer.

8.3.3 ACTIONS IN RESPONSE TO NONCONFORMING PRODUCT AFTER DELIVERY

If a non-conforming product is discovered after delivery, information will be provided to the customer through a warning sheet describing the problem and potentially its correction.

8.3.4 REWORK

The rework of a non-conform product is conducted through a rework order (OR) establish by the Prod. Dir. or the QA Dir.

8.4 ANALYSIS OF DATA

All data is collected in each of the process to calculate the QMS operation indicators per list *INDICATOR*.

All these indicators are regularly reviewed by the area directors. These indicators are reviewed and documented at least once a year during the management review per procedure *MANAGEMENT REVIEW*.

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8.5 IMPROVEMENT

8.5.1 GENERAL

Corrective and preventive actions (ACP) are treated as documented in the procedure *CORRECTIVE & PREVENTIVE ACTION*.

Their follow-up is conducted by the QA Dir. They are raised from the moment that their need is established and justified level of risk or a financial plan.

8.5.2 CORRECTIVE ACTION

A corrective action aims to eliminate a cause of a non-conformity.

A corrective action can be raised by:
- Internal audit.
- Customer audit.
- Surveillance/certification audit from a notified body.
- Audit or inspections from a competent authority.
- Audit from a customer notified body.
- Non-conformity from external subcontracting or internal manufacturing.
- Customer complaint.
- Market feedback.
- Risk assessment.
- Management review.

The procedure *CORRECTIVE & PREVENTIVE ACTION* describes the corrective action management.

8.5.3 PREVENTIVE ACTION

A preventive action aims to eliminate a cause of a potential non-conformity.

A preventive action can be raised by:
- Evolution of a law, norm or standard.
- Internal audit.
- Customer audit.
- Surveillance/certification audit from a notified body.
- Market feedback.
- Risk management.
- Management review.
- Management decision.

The procedure *CORRECTIVE & PREVENTIVE ACTION* describes the preventive action management.

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9. ANNEXES

9.1 ANNEX # 1 - QUALITY POLICY

We seek to ally our expertise in traditional micromechanics with state of the art technologies to produce small tubular articles in the shortest timeframes. We offer an consistent approach with the performance required by the customer while focusing on streamlining the manufacturing process. Our quality management system takes account of our current market position.

The general objectives of our company strategy are as follows:

- Continuous improvement of the quality management system.
- Satisfaction to customers requirements and applicable regulatory requirements.
- Our quality management system must be both user-friendly and easy to manage.
- Management by event and provision of all the technical and human resources necessary to ensure the seamless interaction of the various processes in the company in the framework of a quality management system certified in accordance with the standards IS0 9001, IS0 13485.
- A corporate culture based on dialogue and the flexibility of personnel.
- Retaining employees through empowerment based on appropriate theoretical and practical training.
- An efficient sales service guaranteeing the rapid exchange of information and a single point of contact.
- Custom made products which fully meet the customer's requirements as cost effectively as possible.
- Manufacturing, organized on the basis of flexible independent production workshops.
- Improvements to the working environment, the safety of personnel and the infrastructures.

In relation to events throughout the year, these general objectives materialize into precise objectives, which are reviewed during the management review and meetings. These objectives are implemented in the form of actions and projects. All concerned employees are involved to make their individual contribution.

The General Management supports all the steps aimed at implementing the policy and objectives described above.

Ecublens, the 10th of Octobrer 2023

CEO

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9.2 ANNEX # 2 - LIST OF QMS PROCEDURES

The following table lists the 41 QMS organizational procedures (PO) per the list *DOCSMQ.LIS*.

Description	Procedure #
PURCHASING	ACHAT.PO
CORRECTIVE AND PREVENTIVE ACTION	CORRPREV.PO
AUDIT	AUDIT.PO
CHANGE MANAGEMENT	CHANGEMENT.PO
COMMUNICATION	COMMUNICATION.PO
KNOWLEDGE	CONNAISSANCE.PO
RECEIVING QUALITY CONTROL	CONTENT.PO
PRODUCTION QUALITY CONTROL	CONTPROD.PO
QUOTE & PURCHASING	COMMANDE.PO
PACKAGING & LABELLING	EMBALLAGE.PO
PRODUCTION EQUIPMENT	EQUIPROD.PO
EXPEDITION & INVOICING	EXPEDFACT.PO
TRAINING	FORMATION.PO
SUPPLIER MANAGEMENT	FOURNISSEUR.PO
CRISIS MANAGEMENT	GESTIONCRISE.PO
DATA MANAGEMENT	DONNEE.PO
DOCUMENT MANAGEMENT	DOCAQ.PO
IDENTIFICATION & TRACEABILITY	IDENTRAC.PO
INFORMATION TECHNOLOGY	INFORMATIQUE.PO
INFRASTRUCTURE	INFRASTRUCTURE.PO
MATERIAL HANDLING	MANUTENTION.PO
PRODUCT VIGILANCE	MATERIOVIGILANCE.PO
MANUFACTURING METHOD	METHODE.PO
INSPECTION EQUIPMENT	MOYCONT.PO
CLEANING	NETTOYAGE.PO
CLEANING & STERILIZATION	NETSTERIL.PO
NONCONFORMITY & DEVIATION	NONCONFO.PO
URGENCY PLAN	PLANURGENCE.PO
PLANNING	PLANIFICATION.PO
PRODUCTION	PRODUCTION.PO
PRODUCT	PRODUIT.PO
PROJECT MANAGEMENT	PROJET.PO
QUALIFICATION	QUALIFICATION.PO
RECEIVING	RECEPTION.PO
CUSTOMER COMPLAINT	RECLAMATION.PO
HUMAN RESOURCES	RESSHUM.PO
CUSTOMER RETURN	RETOUR.PO
MANAGEMENT REVIEW	REVUEDIR.PO
PRODUCT STOCK	STOCKTERM.PO
STOCK	STOCK.PO
MARKET SURVEILLANCE	SURVMAR.PO