XO CARE A/S

QUALITY MANUAL

ISO 13485:2016

Valid from 2018-12-06

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Content

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INTRODUCTION

The purpose of this quality manual is to inform employees and other stakeholders about the quality management system (QMS) implemented at XO CARE A/S.

Please note that this document gives an overview only. Employees must read and understand QMS procedures relevant for their area.

1 SCOPE

1.1 GENERAL

XO CARE's QMS covers all parts of the company and all processes with influence on quality and safety of products marketed by the company.

XO CARE manufactures the following products (as per 2018-10-01):

- XO FLEX - dental unit
- XO Smart Link (accessory for XO FLEX) – standalone software for configuration
- XO Peristaltic Pump (accessory for XO FLEX) – delivery system for sterile water
- XO Suction Disinfection (accessory for XO FLEX) – disinfectant for the suction system
- XO Water Disinfection (accessory for XO FLEX) – disinfection for procedural water
- XO ODONTOSON 360 – tabletop instrument, ultrasonic scaler
- XO ODONTOSURGE - tabletop instrument, surgery tool for soft tissue handling

Spare parts and consumables for the products mentioned above are also delivered.

1.2 EXCLUSIONS

XO CARE does not manufacture sterile products and implantable medical devices.

2 REFERENCES

The QMS is designed to meet the requirements of Council Directive (EU) 93/42/EEC Annex II to comply with the legislation and regulatory requirements.

A major update of the QMS was introduced in 2018 to meet the updated requirements of EN ISO 13485:2016 "Medical devices – Quality management systems – Requirements for regulatory purposes".

3 TERMS AND DEFINITIONS

The QMS procedures are written in English.
Some terms marked with [] however, are referred to in Danish, just like some instructions are written in Danish.

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4 QUALITY MANAGEMENT SYSTEM

4.1 GENERAL

The QMS is designed in accordance with the requirements of EN ISO 13485:2016 and applicable regulatory requirements and the QMS processes are structured to follow the chapter numbering in ISO 13485:2016 as shown below.

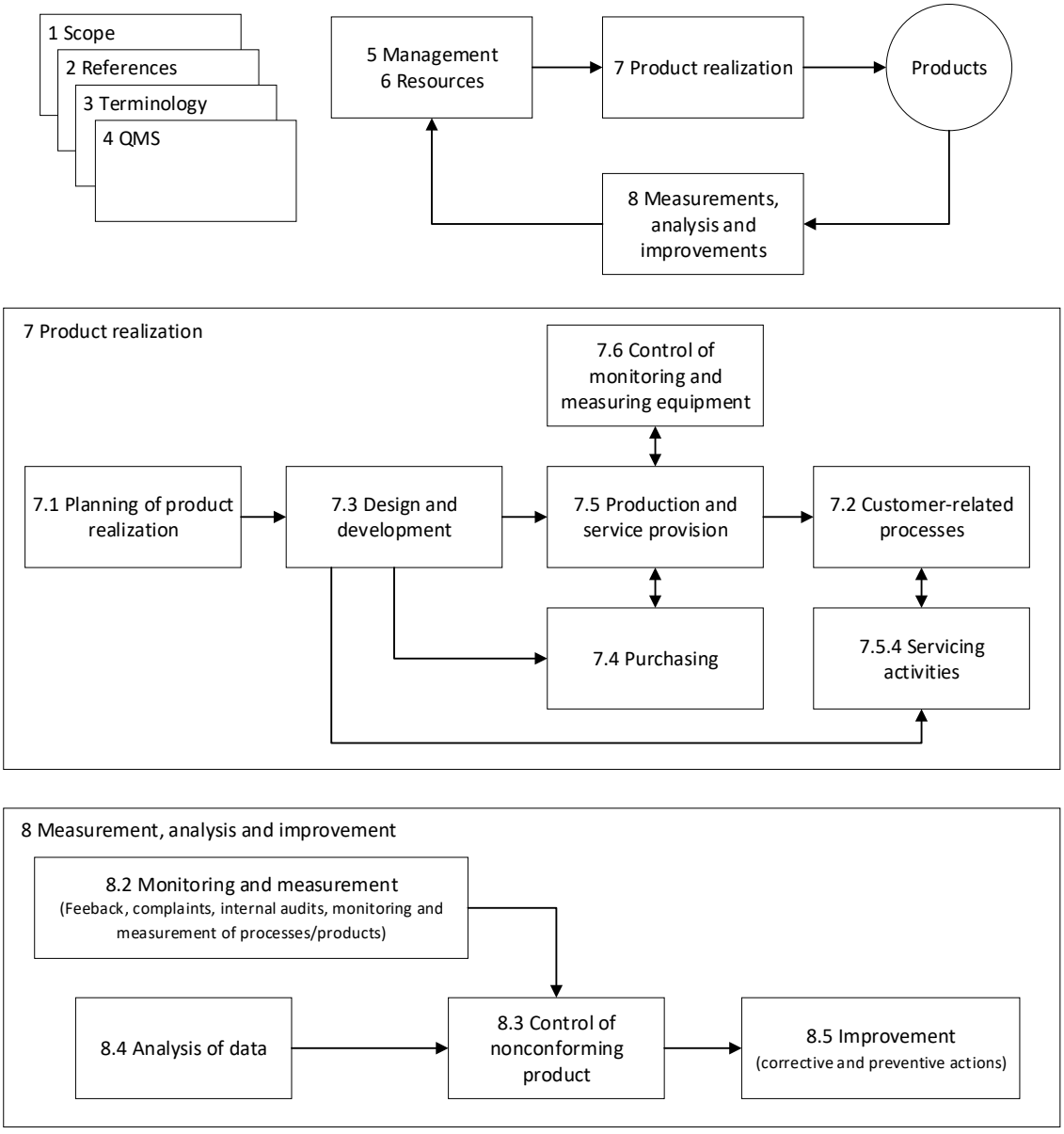

Figure 1 – Processes at XO CARE A/S

As indicated in, Figure 1 resources (6) and management (5) is provided to the product realization (7) in order to ensure that output from product realization is found acceptable according to the expectations from customers and to meet relevant regulatory requirements.

The core of the QMS is the product realization process (7), which can be divided into the following subprocesses: Product realization starts with a planning process (7.1) which delivers input to the design and development process (7.3) and output from this process is transferred

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to production (7.5) for physical manufacturing. Additionally, design transfer contains information to be used for purchasing (7.4) and servicing (7.5.4) to ensure proper training of sales partners, service partners and service technicians (installation and service). During production, the quality of products is ensured through appropriate control of monitoring and measuring equipment (7.6). Output from the production is delivered to the customers, and appropriate customer-related processes (7.2) are established to ensure that important feedback regarding products are fed-back into the organization.
Products are maintained throughout the entire product lifetime and will be subject to continuous measurements, analysis and improvements/corrective and preventive actions (8) (post-marked surveillance activities) in order to constantly improve product quality and ensure compliance with regulatory requirements.

As required by ISO 13483:2016 a risk-based approach has been used throughout this QMS.

The processes described in Figure 1 are performed internally at XO CARE or outsourced to suppliers or sales and service partners as described below in Table 1.

Table 1 – Outsourced processes

Process
Sale of products
Installation of products that require installation
After sales service of products that require installation
Repair of products that require installation
Manufacturing of XO specified components

The control of outsourced processes shall be proportionate to the risk associated to the process/product involved is described in the QMS.

All IT systems used in the QMS shall be identified and the responsible employee shall – approportionate to the risk associated – validate the software prior to the initial use or after changes to the software.

4.2 DOCUMENTATION REQUIREMENTS

The QMS elements are divided into 8 categories:

I. Quality manual (this document)
II. Procedures
III. Instructions
IV. Work instructions – incl. inspection and test instructions
V. Forms
VI. Templates
VII. Databases
VIII. Medical device file

A procedure describes how a process is accomplished and by whom, and who has responsibility for individual steps in the process.

Instructions describe in details how a specific task shall be handled. Instructions are identified with "I" and a serial number enclosed in {} as for example {I-0001 End customer satisfaction survey}.

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Work instructions contain detailed step-by-step instructions on how to accomplish a specific – mainly manufacturing – job, task or assignment. Work instructions may include inspection and test instructions that describe how a product or process is inspected and/or how the products are tested. Work instructions are identified with "WI" and a serial number enclosed in {}[1].

Forms are used for data collection or control of a process. Forms are identified with "F" and a serial number enclosed in {}.

Templates are used to assure standardized documents and procedures. Templates are identified with "T" and a serial number enclosed in {}.

Databases contain and structure information relevant to the QMS. Databases are identified with "D" and a serial number enclosed in {}.
An important database is {D-0015 Instructions, templates and forms} that contain a list of all instructions, work instructions, forms, templates and databases belonging to the QMS.

For each product manufactured, XO CARE shall create and maintain a medical device file with a description of the intended use, the medical device classification according to MDD, an overview of the markets/regions where the products are marketed, and a folder with the medical device file used to demonstrate conformity with EN ISO 13485:2016 and compliance with relevant legislation and applicable regulatory requirements.

QMS procedures, instructions and work instructions shall be maintained in Sherlock and other QMS documents in SharePoint – see {D-0015 Instructions, templates and forms}.

QMS documents are created by an author appointed by the process owner and reviewed prior to final approval.
The author shall specify a review-frequency and a person responsible for the periodic review.

When a document in Sherlock is approved, it cannot be changed.
If change is required, a new version of the document shall be created.

All documents and records created as part of the QMS or the medical device file of a product, shall be filed for a certain amount of time depending on the type of document/record and product in question.

5 MANAGEMENT RESPONSIBILITY

5.3 QUALITY POLICY AND OBJECTIVES

This quality policy applies to all activities performed at XO CARE.

Further we shall – in all we do – comply with this QMS and we shall continuously review, improve and maintain the system to ensure that it works effectively.

[1] Work instructions approved before XO CARE's QMS was updated to ISO 13485:2016 are identified according to the previous requirements.

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Management has defined XO CARE's mission as:

> *XO CARE's solutions secure the highest return on investment for dental practices by enabling the practitioners to perform the highest quality treatments on safe and calm patients while protecting the practitioners' health and maximizing their productivity.*

The mission statement emphasizes that dental practices should expect a high return on investment by acquiring dental equipment solutions from XO CARE – even though the initial investment often will be higher than when investing in "ordinary" dental equipment solutions.

The mission statement is made operational by means of the XO WHEEL – a product development and communication tool.

Further a vision has been defined:

> *To be the top-ranking supplier of quality dental treatment solutions.*

By "top-ranking" we do not mean the biggest, but rather the most interesting and forward looking manufacturer of dental treatment solutions.

We shall strive to create and supply products with the best possible quality still maintaining a competitive sales price level.

By quality we mean that the products fulfill their mission (helping dental practices treat patients as explained above), that the products have a good and timeless design, that the materials used are of the right quality and that the finish is extraordinary. For us high quality means that the products are reliable and can be used for many years and therefore live up the customers and the society's circular economy expectations.

In relation to all processes taking place at XO CARE we shall ensure that requirements from customers and authorities are identified and met.

Wherever appropriate risk management considerations shall be implemented to identify possible risks and relevant risk mitigation measures.

The following quality objectives have been decided:

Table 2 – Quality objectives

Objective
The number of satisfied end customers' shall increase with 5 % per year
The customer complaints shall decrease with 5 % per quarter
Warranty costs shall not exceed 1 % of the revenue
More than 95 % of critical spare parts ordered before the end of a working day, are shipped the following working day

The measurement results shall be studied at evaluation meetings and presented to the employees at information meetings.

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5.4 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

Below the organizational structure of XO CARE is defined.

The Management team (indicated with orange color in the figure below) manages the processes handled by the organization.

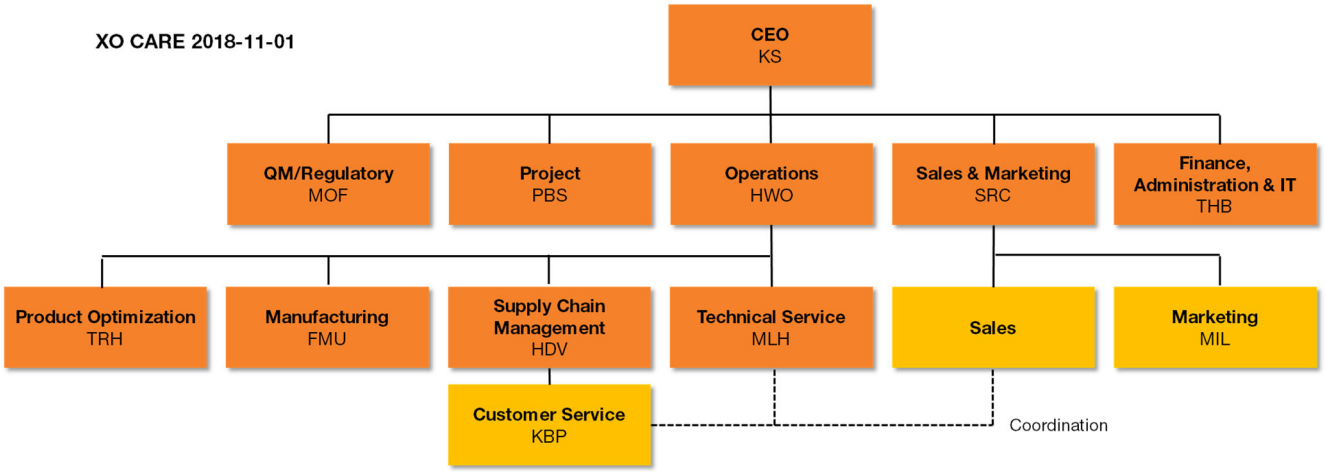

Figure 2 – Organizational structure (2018-11-01)

The organization is structured in a number of teams.

The tasks and responsibilities shall be described in a job profile or a job description.

The manufacturing processes are structured in manufacturing teams and each team is managed by a team leader.

Quality Manager is appointed as responsible for the QMS and must report to the CEO concerning the function of the system and major necessary changes.

Each quarter, Quality Manager organizes an evaluation meeting to evaluate the QMS – especially the system's ability to ensure that customer and authority requirements are met. In addition to the management review meeting at least one management meeting shall be organized each month by CEO. The meeting shall – in addition to general management issues – handle quality management issues.

6 RESOURCE MANAGEMENT

6.2 HUMAN RESOURCES

The QMS has special focus on employee education and/or training and each manager shall make sure that the employees at all time have the right skills to perform the job. Training shall be classified according to the risk associated with the training and the effectiveness of the training shall be documented.

CEO shall at least two times per year arrange an information meeting for all employees.

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6.3 INFRASTRUCTURE

Each manager shall, based on the associated risk, ensure that buildings, workspace and associated utilities, process equipment and information systems relevant for the QMS in the manager's area is designed to enable the employees to manufacture products that fulfill the requirements.

IT Administrator shall document all IT systems used at XO CARE including all relevant information necessary to safely operate and maintain the systems, ensure that that data is protected against unauthorized access and that all data files are backed up.

6.4 WORK ENVIRONMENT AND CONTAMINATED PRODUCTS

All workstations shall be designed so that the employees can work in healthy postures and the lightning shall be designed to assure visible control of the products.

6.5 DATA PROTECTION

Employee data and customer data shall be handled in accordance with the company's data protection policy.

7 PRODUCT REALIZATION

7.1 PLANNING OF PRODUCT REALIZATION

The design and development effort is governed by a stage-gate model that divides the product realization into stages separated by gates. At each gate, the continuation of the process is decided by the management.

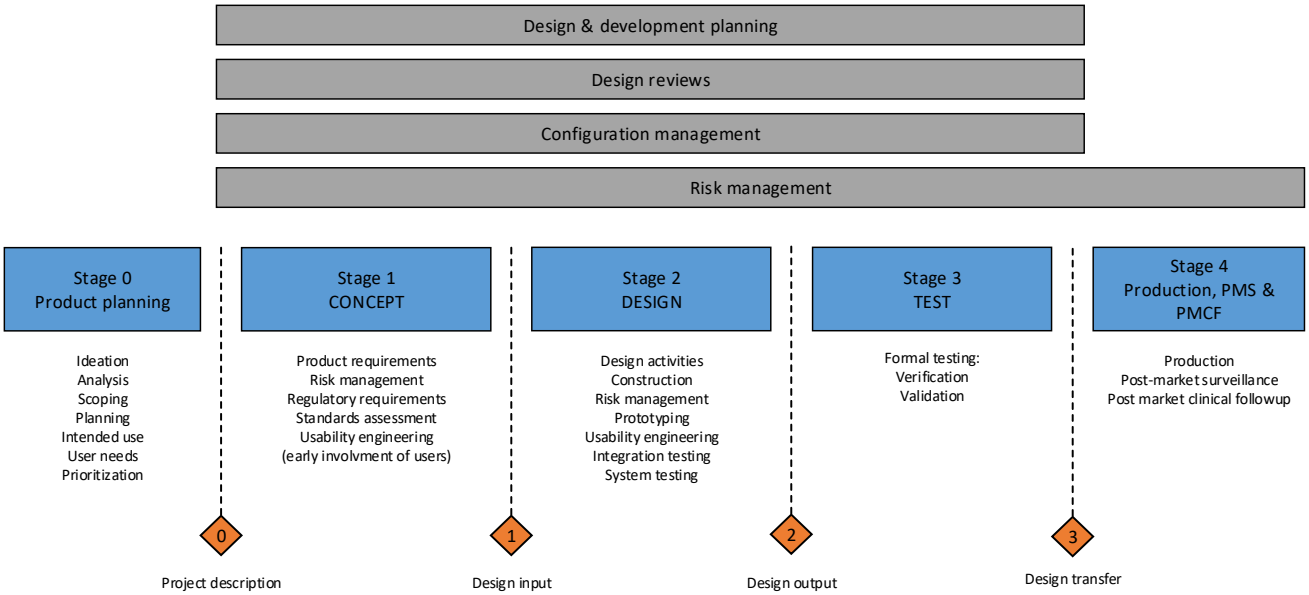

Figure 3 – Stage gate model

The stage-gate model divides the product realization effort into the three following major components, which are executed in the specified order:

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- Product Planning
- Design & Development (CONCEPT, DESIGN & TEST)
- Production/manufacturing + post-market surveillance (PMS) and post-market clinical follow-up (PMCF)

The stage-gate model presented in Figure 3.

7.2 CUSTOMER-RELATED PROCESSES

The products are sold via sales partners and service partners to end-customers that may be small dental practices or large dental practices as shown below in Figure 4.

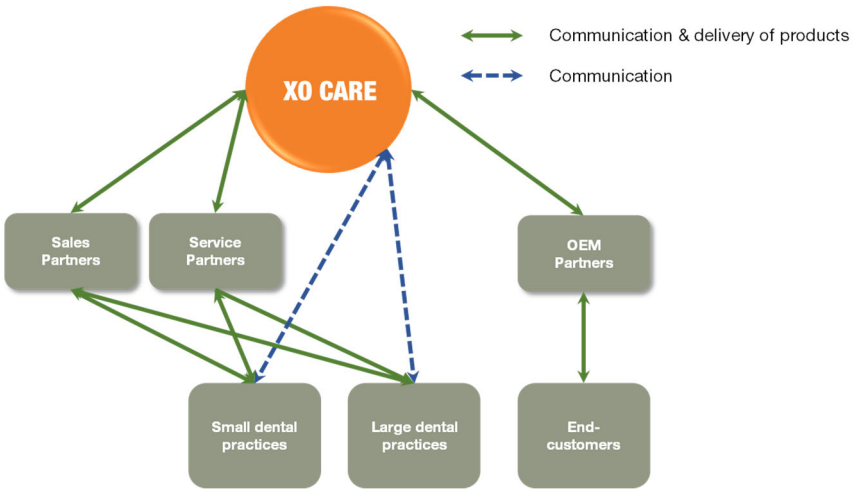

Figure 4 – XO CARE's customers

Products that require installation are installed and serviced via sales partners and service partners.
Service partners handle transport, installation, instruction of end-customers, after sales service and repair of products. Service partners may (passively) sell products to the end-customers.
In addition to the tasks handled by service partners, the sales partners actively sell products to end-customers.
The term customer refers partners or end-customers.

Generally, XO CARE products are not manufactured to meet specific customer requirements but are designed by XO CARE based on communication with customers, ideas created inside the organization, regulatory requirements, feedback and complaints.

Ideas to new products or improvement of existing products are generated when XO CARE employees spend time with customers and other end users, visit dental exhibitions or meetings arranged by dental associations, study dental magazines, other relevant literature and end-customer surveys.

The procedure describes how partners are selected, that a written agreement shall be made, that partner employees shall be registered and trained and how partners shall be reviewed.

Further the CRM system – for storing information on partners, partner employees and end-customers – is described.

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Also, requirements for compilation and communication of price lists, review of customer data and general conditions related to the delivery of the products are defined.

Further the procedure describes provision for processing of customer orders and handling of returned goods.

7.3 DESIGN AND DEVELOPMENT

This section incorporates the requirements for product development and is initiated by a design and development planning as shown in Figure 3.

The purpose of the planning is to ensure that the design process is appropriately controlled and that the quality objectives are met.
Design and development planning is an ongoing activity that continues throughout the entire CONCEPT, DESIGN and TEST stages.

In the CONCEPT phase, product conceptual descriptions shall be elaborated, expanded, and transformed into a complete set of design input requirements which are written to an engineering level of detail.

Design output is the result of the design effort. Design output is generated as output from the DESIGN stage and is the basis for the medical device file.

In the TEST stage, device verification may be executed as a combination of in-house testing performed by XO CARE A/S staff, and tests performed by external third-party test houses.

Design validation shall be performed under defined operating conditions on initial production unit(s), lots, or batches, or their equivalents.

Finally, the project manager shall release the medical device file and transfer the project to production.

The described change management process shall also be used to implement changes to existing products.

7.4 PURCHASING

The first part of this procedure describes how a supplier shall be selected, evaluated and how the collaboration shall be started.

Evaluation of a new supplier shall be done in accordance to the risk of the item to be supplied. Purchased items shall be classified in relation to the potential risk related to the item:

- Critical XO specified components
- Critical components
- Non critical XO specified components
- Non critical components

For critical components – or components where supply failure is estimated to have huge negative economic impact – preferably at least two alternative suppliers of a component or product shall be selected.

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When a supplier is approved a written agreement shall be made and all relevant documents shall be maintained.

When the collaboration with a supplier has been established the procedure described how the purchasing process shall be handled.

All suppliers of critical components and suppliers that supply components/products for more MDKK 1 per year shall be re-evaluated at a frequency corresponding to the associated risk.
If the re-evaluation of a supplier of critical XO specified components and suppliers that supply components/products for MDKK 2 or more per year, shows that corrective actions are required, the re-evaluation shall be followed up by an audit at the supplier's address.

All purchases shall be based on verified and updated specifications.
If a supplier requests to modify the technical specifications of an item this shall be approved by XO CARE.

Depending on the type of supplier and the potential risk associated with the supplied items, the suppliers shall be controlled using one or more of these control types:

- A declaration from the supplier that confirms the supplied items are in compliance with the required specifications
- A test report made by the supplier documenting that the supplied components/products are in compliance with the required specification
- The supplier controls and documents the control of critical components
- The components/products are subject to technical inspection at XO CARE
- The supplier has established a certified quality management system

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 CONTROL OF PRODUCTION

The production shall be planned to match production capacity and customer demand.

When a new product is being developed or an existing product is modified, Project Manager shall in the DESIGN stage of the overall stage-gate model (see Figure 3) in collaboration with Manufacturing establish/revise the production specifications.

A new or modified product is released for manufacturing when an engineering change notice is approved and published.

The engineering change notice form specifies – based on risk assessment considerations – the following:

- If the process shall be described by means of a work instruction
- Special requirements concerning process equipment
- If the work instruction shall include a control activity
- If the work instruction shall include provisions on how to clean the finished product
- Who shall write the work instruction and create models
- Who shall approve work instruction and reference models
- If the employee that shall perform the process needs special training

Work instructions shall be available at the point of use.

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Only the latest versions of the work instructions shall be available and outdated versions shall be disposed.

The manufacturing processes shall constantly be monitored and improved using Lean white board meetings.

It shall be verified that the process equipment chosen, makes it possible to manufacture products with the specified requirements, and if appropriate dedicated tool boxes and tool boards shall be used for a process.
All process equipment that need service shall be serviced as appropriate.

To protect product surfaces, work tables shall be covered with a soft material.
Electronic components and printed circuits shall either be enclosed in antistatic packing or handled on tables covered with antistatic mats connected to protective earth

The manufacturing environment in general shall be clean and the indoor climate shall be comfortable (e.g. temperature air humidity and lightning).
Manufacturing rooms where processes like gluing and soldering is performed shall acceptable by means of ventilation etc.

Stored items shall be handled proportionate to the risk associated with the items.
An item stored in A warehouse shall be marked with item number and assemblies shall be stored at Manufacturing as near as possible to the work station where they are needed.
Nonconforming items shall be stored in C warehouse and shall be clearly marked as nonconforming.
Items that require special storing conditions (e.g. temperature) shall be stored as required in A warehouse and handled according to the FIFO principle.

Sterile products shall be stored as prescribed by the supplier and the packings must not be opened.

The manufacturing processes shall be followed by a control activity (process control) if this is required in the work instruction.

Pre-shipment control with a complete test of functions and electric safety shall be done for the following products:

- XO Units
- XO ODONTOSURGE
- XO ODONTOSON

Spare parts, accessories and consumables shall be verified to comply with specified requirements before delivery.

Monitoring and measurement equipment shall be available where necessary.

All products that shall be transported shall be packed to ensure sufficient protection during transportation and storage.
Painted components shall be packed individually in cell air foam bags or parts-specific packaging.
Printed circuits shall be packed in antistatic bags and large printed circuits shall be packed in special designed printed circuit boxes.

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All consignments shall be marked with relevant customer data and XO's order number.

At delivery it shall be ensured that a consignment is complete, and it shall be controlled that the product specification comply with the customer order specification
If relevant it shall be controlled that accompanying documents are supplied in the language listed on the order.

Return goods may be contaminated and shall be sterilized or disinfected before inspection and repair.

Further the procedure describes how a product shall be phased out.

7.5.4 SERVICING ACTIVITIES

External servicing processes such as installation, servicing and repair of products that require installation (units) supplied by XO CARE are done by partners.

Accompanying documents (instructions for use, installation instructions, service instructions, spare parts lists etc.) shall be designed and maintained.

Critical spare parts (spare part that is necessary for a product to function) shall be identified.

Service notes informing partner service technicians about:
- Product modifications
- New products
- Changes in installation or servicing of the products
- Or other relevant issues

shall be created.

Accompanying documents and service notes shall be posted on xo-care.com and distributed to relevant partner employees.

Technical training programs for partner service technicians in installing and servicing the products shall be created and published.

Major partners shall be audited and it shall be verified that their service technicians are trained, that they have the right tools, that they have enough spare parts in stock, that they only use original spare parts and consumables, that the installation and after sales service is done as required and finally that the partner returns installation reports documenting the address of the end-customer.

It shall be ensured that the installation instructions and installation report include provisions making it possible for the service technician to test that the product functions correctly and to instruct the end-customer in using, maintaining and disinfection the product.

When necessary and at least every 24th month a technical evaluation meeting with service technicians from selected partners shall be organized.

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7.5.6 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

All products sold to customers shall be verified before shipment and production processes shall therefore not be validated.

Installation and technical service on units is outsourced to partners as described in 7.2 and validated by XO CARE as described in 7.2 and 7.5.4.

For each process equipment with software the software shall be validated prior to the initial use or after changes to the software. Such validation shall be proportionate to the risk associated with the use of the software and documented.

7.5.8 IDENTIFICATION

Depending on the associated risk items shall be identified by:
- A unique item number followed up by a short item description
- A marking plate with a unique serial number (units and tabletop instruments only)
- A label with item number and item description in English (items sold to customers)

Further the procedure details the identification of:
- XO specified components
- Casted metal components specified by XO
- Printed circuits
- Patient chairs and operators seats
- XO ODONTOSON and XO ODONTOCURE handpieces
- Software
- Accompanying documents

7.5.9 TRACEABILITY

When an item with a serial number is invoiced to a costumer the serial number is registered on the invoice and stored together with costumer data in Axapta.

Unit data registered in Axapta is transferred to the CRM system and end-customer data from installation report are registered.

7.5.10 CUSTOMER PROPERTY

Customer property shall be stored separate from products belonging to XO CARE and the owner of the property shall be clearly marked.

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

All monitoring and measurement equipment relevant to the QMS shall be identified and listed.

Monitoring and measurement equipment with software shall proportionate to the risk be validated prior to the initial use or after changes to the software.

Monitoring and measurement equipment shall be calibrated with intervals depending on the risk associated with the relevant product.

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8 MEASUREMENT, ANALYSIS AND IMPROVEMENTS

8.2 MONITORING AND MEASUREMENT

After marketing of a product, post-market surveillance shall include feedback from e.g. customers, complaints, nonconformities, technical evaluation and/or installation reports.

Customer complaints shall be registered, and a Project Manager shall be appointed to handle the processing of the complaint.

If corrective/preventive action(s) is required further processing shall be according to 8.5.

The Medical Devices Directives requires certain changes of the device or of the quality system to be notified to the Notified Body.

Internal quality audits shall be planned with a frequency proportionate to the risk of the process.

The audits shall document that quality activities are conducted according to the process described in the QMS, that the QMS is effective and complies with relevant standards and legislation.

Design and development of new products follows the stage-gate model (see Figure 3) and the status of planned deliveries throughout the product development phases is documented with phase audits.

8.3 CONTROL OF NONCONFORMING PRODUCT

All products must pass a pre-shipment control before they are released.

The Quality Manager may force a stop of the manufacturing and deliveries to customers in case nonconformity of a product or process leads to unacceptable risk.

Further the procedure describes how nonconformities originating from supplier faults, construction errors and/or process errors shall be handled.

When a customer complaint is received by XO CARE employee, the employee shall consider if the complaint is justified. If yes, a customer complaint shall be registered, and further processed.

Incidents where a patient or user has been injured shall be reported to National Competent Authorities.

A Field Safety Corrective Action shall be performed, if corrective action is needed to ensure safety of products already delivered.

8.4 DATA ANALYSIS

Based on feedback from customers, manufacturing processes, audits, service reports, and/or suppliers, data shall be analyzed to demonstrate the effectiveness of the QMS.

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8.5 IMPROVEMENT

Improvements to products and processes are based on input from customers and employees. All suggestions for improvements are registered in the idea database.

Improvements which affect product safety, or improvements which are determined to be important by the Management team (e.g. based on data analysis) shall be handled as CAPA according to {I-0020 CAPA}.

The prioritization of improvements shall be based on the associated risk.

Corrective and preventive action shall be accomplished according to {I-0020 CAPA} and the corrective and preventive action shall be proportionate to the effects of the nonconformities.

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