Quality Manual

according to ISO13485:2016

TETCON
TECHNICAL TEXTILE CONCEPTS

Tetcon BV - Ruysdaelbaan 3G - 5642 JJ Eindhoven - +31 40 298 99 55 - info@tetcon-ge.com

Contents

1 Company Policy on Quality

Tetcon Global BV (Tetcon) is working in the field of development and production of evacuation and transfer equipment.

The nature of the activities requires employees with expertise, experience, reliability, accuracy, flexibility, knowledge of- and acuity for quality and focus on customer satisfaction.

The company policy has a focus on the delivery of products and services related to requirements and expectations of customers. Customers are not only assigning us for one or more jobs, but also a partner which we want to build a good relation and really keep this relation at a high level.

Tetcon is proactively working at the best quality of products, processes and procedures. This is a continuing process. Our focus is to work according requirements written down in the Medical Device Regulation (class 1) and the requirements of this QMS according ISO13485:2016.

We, therefore, have a focus on:

- Communication with customers, at all level within the company
- Correct supply of products and services of the appreciated product for customers
- Control and feedback of registered quality registrations, customer complaints, post-marketing activities and where appropriate, corrective and preventive actions

Deviations and complaints are controlled by active engagement of our employees.

To make this more visible, we developed- and we are working according- an ISO13485:2016 system.

This system will be reviewed at a minimum frequency of yearly internal reviews (internal audits and management reviews) and by external audits, what has to be done by accredited organisations

The quality system is written down in a quality manual (QM-01) with relevant procedures (QGP documents) and Forms (FRM documents).

Management will do all efforts to perform according this quality manual.

Eindhoven, July 2020

General Management,

Piet Hezemans

2 Organisation

The scope of the management of Tetcon is to research, develop, produce and deliver evacuating bedridden patients.

Paragraphs of ISO 13485:2016 that are not applicable are:

- 7.5.3 Tetcon is not performing any installation activities
- 7.5.5; Tetcon is not performing any sterilization processes
- 7.5.7; Tetcon is not performing any validation of sterilization processes
- 7.5.9.2 Tetcon is not making implantable medical devices

Our products will meet and exceed the high expectations of a broad range of customers and partners around the world. In order to achieve this, it is the policy of Tetcon to establish and maintain an effective and efficient Quality Management System (QMS) which is developed in collaboration with other managerial positions. The determination of conformity of work to contractual and regulatory requirements is made on the basis of objective evidence.

The company policy on quality is the basis for the determination of quality objectives for the company and for all relevant positions within the company.

Opportunities for the improvement and the need for change of the quality policy and objectives will be assessed on a yearly base by means of a management review. The outcome of this review will become available and communicated to all personnel.

Tetcon personnel are encouraged to communicate ideas for improvement of the QMS system to the management and to the Quality Manager. All ideas for improvement and other issues related to the QMS system will be reviewed during the QM meetings by the management. The findings will be communicated to all (involved) personnel.

All relevant documents of the QMS system will be continuously available to all personnel. Personnel will be notified of all relevant changes to the QMS by the Quality Manager.

Integrated into the QMS are procedures relating to security and confidentiality. These have been included to ensure that client confidentiality is maintained at all times and that possible client data are kept in a secure location when not in use.

Tetcon shall ensure that management and personnel are fully conversant with the company's objectives through an on-going education and training programme for personnel at all levels within the company. Tetcon is aware of the importance of meeting customer requirements. On a regular base Tetcon will collect and measure the customer feedback and aim to exceed the customer's expectations. The QMS of Tetcon is based on the requirements of ISO 13485:2016.

Tetcon's quality manual, general procedures and standard operating procedures shall be available to all personnel, to ensure that work is carried out to the applicable requirements. Specifications for particular jobs are to be made available to the individual worker(s) involved. Throughout all stages of the work, all data and materials pertaining to a job will be clearly identified as belonging to that job.

At any stage of the work schedule, inspections may be held for the presence of non-conforming Issues. Any non-conforming Issue identified at this stage shall be handled in accordance with the written general procedures.

Data and other specifications produced in the course of a job will be recorded on forms compatible with contractual requirements and/or Tetcon Procedures.

3 Management Structure

The Management Structure of Tetcon is as follows:

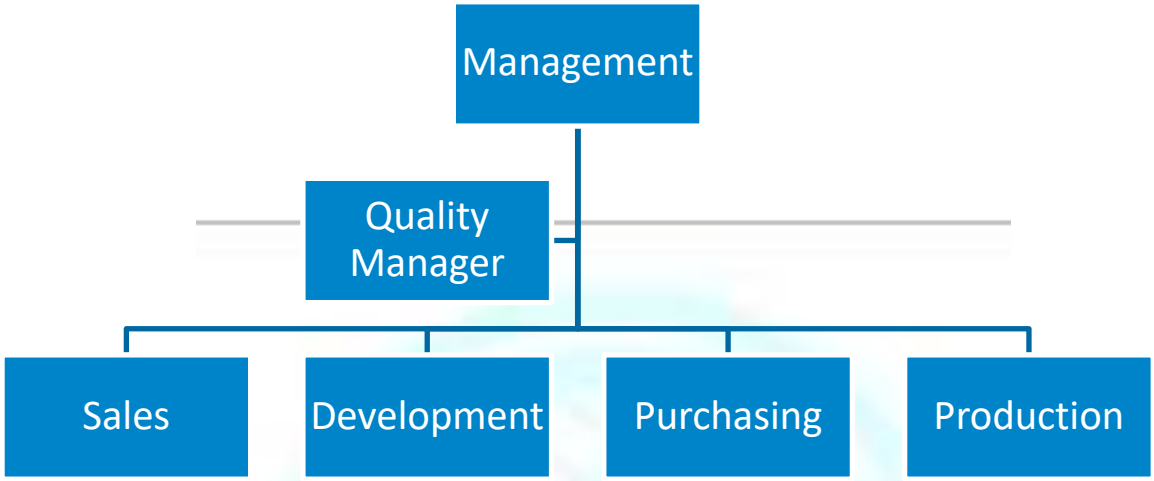

Fig. 1 Organization Chart

3.1 Overall process plan

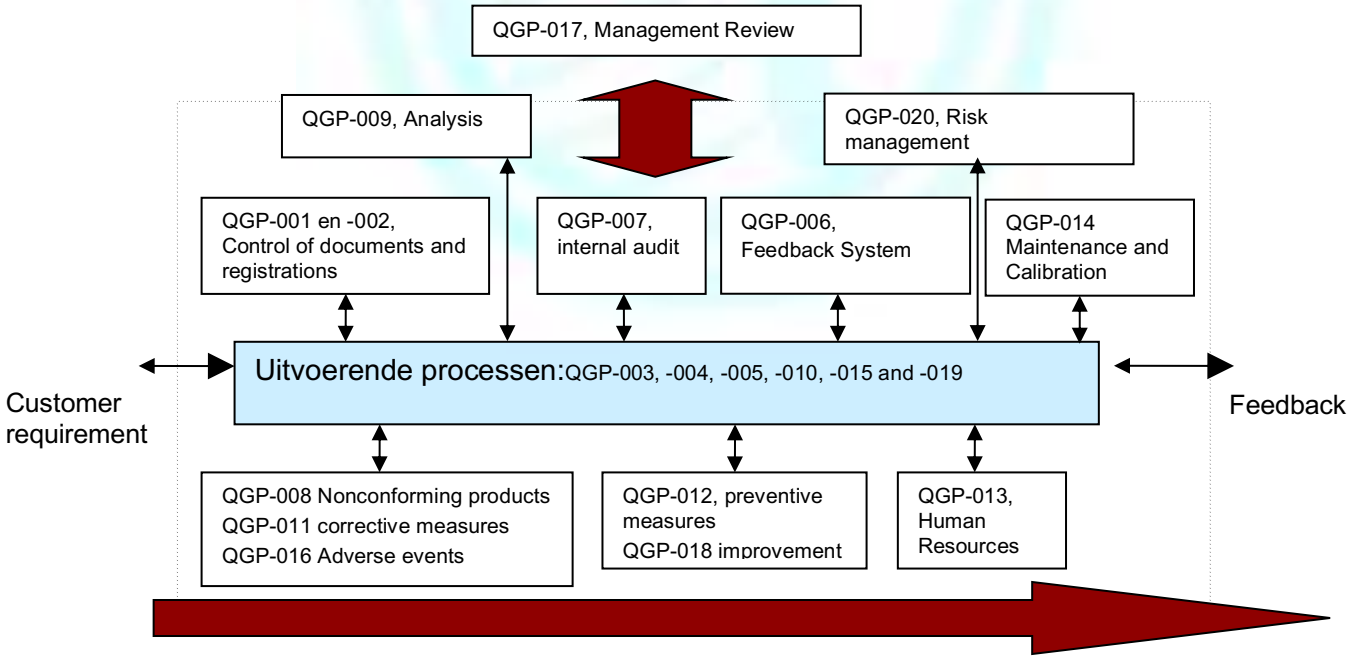

Fig. 2 process schedule and relation with QMS

3.2 Communication structure Internal

Meeting	Attendees	Frequency	Registration
Management Review	Management	Annually	Minutes
QM meeting	Management	4x per year (1x = management review)	Minutes & action list
General meeting	Personnel	Ad hoc	When desired

4 Process and product control

Processes are verified by Quality Management and during Management Review by internal audits and by daily monitoring the performance.

The production process is performed at subcontractors' premises. Monitoring is done by use of document control, local visits / audits and product tests.

Where necessary, processes of Tetcon are validated according QGP-004

5 Personnel

Acquired skills that are necessary for the effective functioning of Tetcon personnel shall be identified, categorised and documented in job descriptions (FRM-005).

Documented evidence of personnel competence is retained. Review of these records shall determine whether personnel carrying out their daily duties require training or additional experience. Competence shall be gauged by:

1. Attendance at appropriate training courses, internal SOP training, conferences and workshops;
2. Certification from recognised examinations;
3. Comparison with work by experienced personnel within Tetcon;
4. Yearly (voluntary) performance interviews;
5. Ability to fulfil job descriptions.

Personnel appraisal records, past experiences and personnel wishes are maintained by the general manager and used to identify training needs.

Method for identifying training needs is covered by a documented procedure QGP-013.

6 Contract Review

Tetcon offers medical devices that meet each customer's needs. These products will be described in promotional folders and on the organization's website: www.tetcon-ge.com or www.s-capeplus.com.

The requirements differ from one customer to another and from one contract to another; therefore, each project requires quotation through a specific contract.

During the quotation process, Tetcon will support the customer to apply to all applicable national and international laws, regulations and agreements, related to the specific project and requirements.

The customer can accept the proposal by returning a signed copy, accompanied by a Purchase Order (PO) number. This PO is recorded and reviewed to establish that the requirements of the order are adequately defined and documented, any differences from the proposal are resolved, and Tetcon is capable of fully satisfying the customer's requirements.

In addition to the original proposal specifications, the customer may also request additional or variational work to be performed by Tetcon. In this case, the work content is documented and agreed with the customer prior to execution to ensure that no ambiguity exists. Changes to contracts, whether initiated by Tetcon of by customers/suppliers/subcontractors are reviewed and incorporated into the applicable specifications. The sales process is described in QGP-010.

7 Risk Management

Risk Management is an on-going process during all processes within Tetcon and is done according requirements of ISO 14971. During new product development also a FMEA (Failure Mode and Effect Analysis) is done on both the product and the production process. Risk management process is described in QGP-020.

8 Activities

Tetcon is able to develop and produce medical devices, mainly class 1.
The organisation is a legal manufacturer for these class 1 medical devices, performs repair and maintenance activities regarding these products and acts as a distributor for other legal manufacturers.

- The development process is described in QGP-003. Where applicable and needed, development stages are described in SOPs.
- General production process is described in QGP-005.
- General Maintenance process is described in QGP-014.

9 Security and Confidentially

All materials and data supplied by the client and generated by Tetcon on behalf of the client will be deemed confidential. When not in use, all hardcopies of documentation relating to products and production will be filed in a secure place (filing cabinet at Tetcon), digital copies are stored on a protected cloud server and a "clean desk" policy will operate.

Tetcon employees will not communicate (either verbally or in writing) the work on which they are currently (or previously) engaged, except with other (*designated*) Tetcon employees and the client in question.

10 Purchasing

Quotations are requested from several suppliers, which are listed in the 'Accepted Supplier List' for critical purchases (those who have an influence on Tetcons' performance in relation to Tetcons' customers). Subcontractors are evaluated in the same way.

Suppliers of products, materials and services, where unspecified by a customer contract, are selected on their ability to meet the company's requirements given due consideration to the quality, statutory obligations, timescale and cost. A list of approved suppliers and subcontractors is maintained which is compiled on the following criteria:

- Previous performance in supplying to similar specifications and requirements;
- Compliance with an approved third-party product/ quality registration scheme;
- Recommendation by other similar purchasers or manufacturers of equipment;
- A trial order and evaluation of performance.

All supplies and sub-contracts are subject to an authorized Purchase Order providing full clarification of the type and extent of supply. Should a supplier, not appearing on the Approved Suppliers List, be proposed they will be analyzed by capability and subject to acceptance on the authority of the general manager.

The review of the suppliers is performed as an input for the Management Review. Suppliers who continue to fail to meet Tetcons' requirements will be notified and could be replaced by other parties.

Purchasing is covered by QGP-015

11 Identification & Traceability

All documents used in the process of contracted work will be clearly identified, with respect to client, work subject, and internal Tetcon job number. Identification is covered by a general procedure (QGP-19). Returned products identification (and isolation) is covered in the procedure QGP-008 (Control of nonconforming products).

Traceability is enabled by a unique numbering system and covered by QGP-019. This procedure defines the extent of product traceability, components, material and work environment conditions and records for distribution.

12 Internal control of Non-Conforming product

Non-conforming products are identified and controlled to prevent its unintended use or delivery. The controls and responsibilities are covered by a documented procedure QGP-008.

13 Improvement

Tetcon shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

There shall be continuous review of clients' complaints and comments on Tetcon product to detect and eliminate causes of non-conformance. All Tetcon procedures and activities will be reviewed and amended to eliminate causes of non-conformance. If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved. Improvement is covered by a documented procedure QGP-018.

14 Corrective Actions

Where non-conformities arise, Tetcon shall take action to eliminate the cause of nonconformities. The quality manager shall define the corrective action necessary, and the original employee shall be responsible for the implementation of that corrective action. The quality manager shall also ensure that the corrective action has been taken, and that it has been effective, that procedures are amended to take account of this corrective action and that such amendments are properly recorded. Method for corrective action is defined in documented procedure QGP-011.

15 Preventive Actions

Where a person identifies opportunities to prevent potential non-conforming issues, he/she shall report this to the quality manager. The quality manager shall identify, in consultation with the originator, the cause of the potential non-conformance and take steps to ensure that preventive actions are taken.

The originator shall be responsible for taking the preventive action specified.

The quality manager is responsible for any changes necessary to Tetcons' Procedures.

There shall be a continuous assessment of clients' complaints to detect and eliminate causes of potential non-conforming issues.

Method for preventive actions is defined in a documented procedure QGP-012

16 Document control

Documents (and specifications) relating to a work order or contract are maintained. Reports shall be revised in accordance with client's requests, but subject to the specifications accepted prior to dispatch. Within Tetcon, revisions are recorded and approved. The issue, recall and re-issue of reports and supporting documents are under the jurisdiction of the general manager, or his designated representative. The actual documented management system and the table of contents assist in the identification of current revisions of documents.

Tetcon procedures are documented and accessible to all employees of the company, to ensure the effective functioning of the Quality Management System. Records will be kept of changes to internal manuals and documents. All obsolete or outdated documents shall be withdrawn from all existing locations and disposed of in an appropriate manner.

Method for document control is defined in QGP-001

17 Quality Records

Legible quality records must be generated and maintained to demonstrate the effective operation of the Quality Management System, and the achievement of Tetcon quality standards. These records shall include but are not limited to:

- Management Review
- Registrations of effective functioning of Tetcons' personnel,
- Information of process performances,
- Details of non-conforming issues,
- Preventive and Corrective actions taken,
- Details of clients' comments (e.g. complaints, customer satisfaction).

These records shall be readily retrievable and shall be reviewed by the quality manager for the purpose of identifying adverse trends or the improvement of systems. Quality records shall be kept for the time specified in the record retention table and shall be made available (subject to confidentiality) upon request from a client. The method of disposal of quality records shall be defined in QGP-002. Records shall be stored in a suitable environment, so that deterioration or loss of records is minimised. Quality records may be submitted to a Certifying Authority or Regulatory Body for review, subject to the confidentiality requirements of Tetcons' clients.

18 Internal Quality Audits

The general manager shall arrange that a programme for evaluating the adequacy of all aspects of Tetcons' Quality Management System is made. This programme defines:

- The activities, systems and procedures to be audited,
- The personnel qualified to perform the audits (internal and/or external),
- The frequency of the auditing,
- The method of reporting the findings,
- The method for agreeing and implementing corrective action

The audit shall include evaluations of:

- Activities, processes, work areas, and data produced,
- Quality practices, systems, procedures and instructions,
- Certification, documentation and recording.

Audits are carried out by appropriately trained personnel who are not directly responsible for the area being audited. Audits shall be performed according to QGP-007. Managers responsible for the areas or departments

being audited shall review the documented audit results, examine root cause and correct deficiencies identified in the audit report. All action taken to correct deficiencies shall be re-audited to verify compliance.

The reports of the internal audits shall be used by management to review the effectiveness of the Quality Management System.

19 Feedback system

Tetcon monitors information relating to whether the organization has met customer requirements. The method for this feedback system is defined in a documented procedure QGP-006.

Feedback means, but are not limited to:

- Phone call records
- Surveys (online or on paper)
- Visit records
- Complaint records
- Recurrent orders from customers

20 Management Review

The entire Quality Management System as detailed in the Quality Manual is subject to review every year by the general manager and quality manager during management review meetings to ensure its continuing suitability and effectiveness in satisfying the requirements of ISO 13485:2016 and the Company Policy on Quality.

The agenda for these meetings includes the review of: (among other things) performance of the QMS, new or revised regulatory requirements, the quality manual, internal quality audit reports, status of preventative and corrective actions, status of actions resulting from previous management review meetings, non-conformance reports, customer complaints, resource and training requirements and recommendations for improvement.

The output of the management review includes decisions and actions related to improvements to maintain effectiveness, improvement of product related to customer requirements and resources needed.

The method for the management review is defined in QGP-017

21 Document History

Revision	Date	Author	Remarks
1.0	2020-07-01	R. Stokmans	First issue