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| saft | **Generic Quality Assurance Plan**<br>**NF EN ISO 13485: 2012**<br>**Batteries for medical devices** | | REGISTERED ISO 13485 |
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| Subject: Generic Quality Assurance Plan dedicated to medical applications (ISO13485) | |


Summary:
This document describes the specific issues not included in the QSE Manual MQ44100 (Quality, Safety and Environment) of the Civil Electronics Division regarding to the applicable rules, procedures and documents to meet the ISO 13485:2012 standard.
The implementation of this Quality Assurance Plan is effective from its date of validation. Therefore, all the projects prior to this date will not be subject to the strict application of this standard.


| | Nom/Name | Fonction/Function | Signature | Date |
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[1] *Fill the appropriate box.*

## MODIFICATION OF THE DOCUMENT

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## Summary

# 1. Scope

This document describes the specific issues not included in the QSE Manual MQ44100 (Quality, Safety and Environment) of the Civil Electronics Division regarding to the applicable rules, procedures and documents to meet the ISO 13485:2012 standard.
The implementation of this Quality Assurance Plan is effective from its date of validation. Therefore, all the projects prior to this date will not be subject to the strict application of this standard.

In addition and for reasons which are specific to the overall understanding of the Quality Management System applied within the Civil Electronics Division, several general issues are addressed in the chapters below.

## 1.1 Application scope

This Quality Assurance Plan is applicable to the Civil Electronics Division. It covers the design, development, manufacturing, testing and delivery of batteries for medical devices power supply. The development and the production of cells are excluded from the scope.

## 1.2 Submission and approval

This document is subject to internal approval.

# 2. Applicable documents

Saft quality procedures (data in annex) are mostly referenced in the QSE Manual (MQ 44100). The "new" procedures have been specially created to meet the additional requirements specific to the ISO 13485 standard. These procedures are listed in annex.

The quality management system is based on the following documentary structure:

- Quality General Procedures: PGQ 46XXX
- *These procedures describe the general functions of the quality system, in accordance with the specifications of the standards ISO 9001:2008 and ISO 13485 :2012 and HSE.*
- Operational Procedures: POP 47XXX
- *These procedures describe the methods of implementation of the previous PGQ.*
- Documents/records models: MDLxxxxx

Other documents: Correlation matrix ISO 13485:2012

## 2.1 Saft applicable documents

Civil Electronics QSE Manual MQ44100
Quality Assurance Plans – General principles of establishment and management: POP 47040

## 2.2 Reference documents

ISO 13485:2012 and ISO 14971:2007 standards
The quality procedures are referenced in the Quality Manual.

## 3. Abbreviations

**RCD :** Revue Critique de Définition (Critical Design Review)
**EC :** Division Electronic Civil Poitiers
**LDR :** Liste de Documents Requis (List of the Documents Required)
**FA :** Fiche d'Anomalie (Anomaly Sheet)
**N/A :** Non Applicable (Not Applicable)
**QSE :** Qualité / Sécurité / Environnement (Quality / Safety / Environment)
**NC :** Non Conforme (Not Compliant)
**RNC :** Rapport de Non-Conformité (Non-Compliance Report)
**RDP :** Revue de Design Préliminaire (Preliminary Design Review)
**LS :** Livret Suiveur (Log book)
**MQ :** Manuel Qualité (Quality Manual)
**POP :** Procédure Opérationnelle (Operational Procedure)
**PGQ :** Procédure Générale Qualité (Quality General Procedure)
**DM :** Dispositif Médical (Medical Devices)
**EPI :** Equipement de Protection Individuel (Personal Protective Equipment)
**PSR :** Product Specification Request
**RFA :** Request For Approval

# 4. Quality management system

## 4.1 General requirements

The quality general provisions are described in the QSE Manual MQ44100 and comply with the requirements of the standards ISO9001: 2008; OHSAS 18001: 2007 and ISO 14001: 2004

The certificates are available and can be consulted on our website: www.saftbatteries.com (Quality section)

The authorities and functions of the various employees are described in the QSE Manual MQ44100, the job descriptions and also through the organization charts available on the intranet of the site of Poitiers.

## 4.2 Documentation

### 4.2.1 Generalities

The records shall be established and kept to provide a proof of compliance with the requirements and of the effective operation of the quality management system.
Saft undertakes to keep all the records related to the products, for a minimum period equal to the life of the product, according to the PGQ 46005. The documents are archived on the network to keep them over a long period.
Saft ensures a regulatory monitoring via Arist body, for the indexes ICS 11.040 (medical devices) and ICS 29.260.20 (electrical equipment for explosives atmospheres).

### 4.2.2 Quality manual

The QSE Manual MQ44100 is elaborated in accordance with the ISO 9001:2008 standard and includes the application scope of the quality management system, including details and justification of exclusion and non-application.

### 4.2.3 Control of the documents

The provisions related to the management and the control of the documents required for the QSE system are the subject of the PGQ 46005 procedure.

These provisions apply to the various life stages of:

- The internal documentation: elaboration, approval, dissemination, modification, preservation and disposal
- The external documentation: receipt, dissemination, archiving and disposal

The documents related to the product quality assurance (industrial files) are managed in accordance with the provisions of the specific procedures:

- POP 47106: Creation and management of the industrial files
- POP 47104: Management of the definition files
- POP 47049: Control of the technical documentation (excluding IF)

#### 4.2.4 Control of the records

The Quality General Procedure PGQ 46016 specifies the list of the records that must be kept.

The procedure also specifies the functions responsible for these records, the minimum period of retention and the rules of disposal. In addition, it defines the methods ensuring the control of the records issued and/or retained by the suppliers.

In accordance with the contractual or regulatory requirements, some records are available for review by customers or by the relevant authorities, if the rules of the protected and classified documents are complied with (POP 47067).

The medical project-related records will be kept for a period of 10 years in both our services and in the services of our suppliers.

## 5. Management responsibilities

### 5.1 Management commitment

The QSE policy of the Division is defined and annually reviewed as part of the management reviews. This policy is part of the QSE Manual MQ44100 and is displayed in the various internal communication areas.

Through the creation of this generic Quality Assurance Plan and related documents, the Management wanted to reinforce its actions in the medical field and thus expand its business.

### 5.2 Customer focus

The customer's needs and expectations are determined at different phases of the processes

- Regarding the batteries, the customer need is analyzed and treated through the PSR process (Product Specification Request), implementing all the skills required for an efficient treatment of the customer's needs (implicit/explicit). These skills gather the sales and marketing departments, the application engineering and the battery engineering and design department.
- The customer satisfaction is evaluated (see 8.2.1 customer satisfaction)

### 5.3 Quality policy

The Quality policy is defined by the Management of the Division, on the basis of:

- The strategic approaches of the Saft group,
- The environmental and safety guidelines of Saft,
- The objectives and purposes specific to the Division,

This policy is formalized and Quality objectives are defined by the Management at the beginning of each year.
The policy and the objectives are reviewed at least once a year, during the management reviews.

### 5.4 Quality Management System planning (QMS)

The provisions described in the QSE Manual MQ44100 and implemented, still apply to the ISO13485 standard, without other specific measures.

### 5.5 Responslbility, authority and communication

#### 5.5.1 Responsibility and authority

The relationship between all the people who manage, implement and evaluate the tasks affecting the quality, are documented and communicated in the Manual MQ44100, job descriptions, internal memorandums and organization charts available on the intranet of the site.

#### 5.5.2 Management representative

The Quality Manager is the representative of the Management of the Division. As such, he has the responsibility and authority to:

- Ensure that the processes necessary for the Quality Management System are established and maintained,
- Ensure the implementation and the compliance with all the rules, procedures and quality management processes, report to the Division Management (especially during the Management Reviews) information about the Quality Management System functioning and suggest the necessary improvements,
- Promote the consideration of the requirements and customer satisfaction by all the functions of the Division,
- Represent the Division before external bodies for matters related to the Quality Management System,
- Resolve issues related to quality and to refuse the achievement of milestones during the development phase, or to stop the manufacturing of a product in case of non-compliance with the quality requirements.
- Ensure customers and staff awareness of regulatory requirements.

The Health Safety and Environment Manager is the representative of the Plant Management. As such, he has the responsibility and authority to:

- Ensure that the processes necessary for the Health Safety and Environment system are established and maintained,
- Ensure the implementation and the compliance with all the rules, procedures and Health Safety and Environment system processes, report to the Plant Management (especially during the Management Reviews) information about the functioning of the Health Safety and Environment system and suggest the necessary improvements,
- Stop an activity in case of serious and imminent danger,
- Promote the consideration of the requirements and of the stakeholders' satisfaction by all the functions of the Plant,
- Represent the Management before external bodies for matters related to the Health, Safety and Environment Management System.

For the subjects related to the environment, he relies on an environmental coordinactors network within the departments and units. The coordinactor's missions are described in §2.5.2.

Regarding the Health and Safety at Work, the Safety and Environment Manager works closely with the managers. These specific powers are formalized in each job description.

### 5.5.3 Internal communication

The internal communication process (PGQL 033) describes the organization of:

- The communication of information related to the company to the staff
- The coordination and organization of the communication within the company
- The feedback and the staff involvement through the communication

## 5.6 Management review

### 5.6.1 Generalities

The requirements are included in the quality management process through the PGQ L032. Moreover, the records of the Management reviews are kept (§4.2.4).

In addition to the Management Reviews carried out in accordance with the requirements of the ISO9001 standard, the Civil Electronics Division provide for an annual Management Review specific to the medical devices. A targeted steering committee (ISO13485) consisting of members of the Executive Committee and main Managers such as Project Manager, Head of Unit has been set up.
This review targets the development, manufacturing, risk analysis and customer satisfaction measurement specific to the field. Conversely, it does not provide for the review and the measurement of the effectiveness of all the processes already covered by existing provisions defined in the QSE Manual MQ44100.

### 5.6.2 Inputs review

The main points of the review agenda:

- Overview of the actions defined during the previous reviews,
- Internal and external audits and their results,
- Business prospects (new projects),
- Products compliance indicators,
- Customer satisfaction indicator,
- Treatment of the initial corrective and preventive actions of the anomaly sheets
- Customer information such as Quality claims
- Changes that could affect the Quality Management System and particularly the Generic QAP of the batteries for medical devices,
- Recommendations for the improvement the development of the Quality Management System
- New or revised regulatory requirements based on the standard monitoring in place

### 5.6.3 Outputs review

After examining each point, the ISO13485 Steering Committee decides on the actions to be taken:

- Revision of the objectives and possibly of the QSE policy of the division,
- Improvement and maintenance of the management systems efficiency in place,
- Improvement of the products according to the customer's requirements,
- Definition of the resources required,
- Capitalization of the know-how (feedback)

# 6. Resources management

## 6.1 Provision of the resources

The planning of the resources required for the activities, particularly for the implementation of the QSE Management System and the maintenance of its efficiency, is done during the preparation of the budget (PGQL021 process "organization management").

## 6.2 Human resources

### 6.2.1 Generalities

The process of "making Human Resources available" is described in the procedure PGQL 030. Its main objective is to set up the necessary resources to control and improve the output achieved through the recruitment, training and skills development.

### 6.2.2 Skills, awareness and training

The units and services express their staff requirements in terms of skills and quantity. These requirements are collected and analyzed by the Human Resources department that decides to recruit and/or train staff. A training plan is established annually, it is the key driver of the willingness to increase the skills.

The Human Resources function keeps a history of the trainings and of the evaluations of these trainings. A review of the effectiveness of these training actions is established once a year. The PGQ L030 aims to provide within the timeframe agreed, in quantity and in quality, the staff necessary to implement the tasks of the Units and Departments for the entire site of Poitiers.

The verification of people's abilities regarding to the skills requirements of their jobs is performed by the hierarchy of the function (POP 47019: "Staff Qualification and Certification"). The records of the operators' individual qualifications are made through the skills matrices.

The staff is aware of the relevance, the importance of its work and its contribution to the achievement of the objectives: Quality, Health Safety at work and Environment during the periodical meetings of the Departments and Units. Displaying the various indicators in the communication areas contributes to this awareness.

Regarding the operations carried out in the context of the manufacturing of the batteries integrating medical devices, a training specific to the ISO 13485 standard requirements is provided to the staff concerned. For the operators, this training is recorded and monitored in the adaptability matrix and for the stakeholders, it is archived in the Human Resources Department.
In case of change in the requirements and during the Management Review, the training module may be revised and another training provided to maintain the level of the stakeholders.

## 6.3 Infrastructures

The investment and maintenance needs relating to the infrastructures necessary to achieve product conformity are analyzed during the preparation of the budget (see § 6.1).

The equipment maintenance activities are planned and described in the procedure 47020 "Maintenance of the equipment".

The infrastructures include:

- The buildings, workspaces and related facilities.
- The equipment related to the processes.
- The "support" departments such as the logistics and the means of communication.

The "Provision of resources" process (PGQL031) describes the activities related to the implementation of new industrial facilities, and associated milestones. There are no special requirements specific to the medical field on this point.

### 6.4 Work environment

The electrochemical lithium cells technology requires that the constituents' preparation and the cells assembly phases be carried out in the dry room which temperature and humidity rate is set and controlled. In this environment and more generally (all areas of activity), the staff must wear the appropriate PPE specified in the safety sheet related to the station (gloves, goggles, white coat, safety shoes,…).
The 5S approach is applied on all the activities of the site. This allows to improve, on a continuous basis, in terms of knowledge of the work environment, cleanliness of the workstations, ergonomics, avoid the risk of errors,…
The aisles between the workstations must be cleared in order to facilitate the access, the movements and the evacuation of the staff in case of emergency.

## 7. Product manufacturing

### 7.1 Planning of the product manufacturing

The planning of the product realization is part of the batteries development processes PGQL035. The provision of means for the batteries manufacturing, which mainly concerns the production and the provision of the tools and jigs, is integrated to the same process. The process for the provision of the industrial means PGQL031 deals with the means requiring bigger investments such as the industrial lines.

The main issues addressed at this stage are:

- The products requirements, defined in the definition files. They include the products, components and sub-assemblies drawings, the bill of material, the technical specifications and the imposed processes. The Packaging Instructions (PDE) is part of the Definition File.
- The audit, control and testing, as well as the documents and records required, defined in the work instruction, provide details about the production and control operations necessary for the realization of the product, through the instruction sheets. The control sheets provide details about the nature, frequency, limits and mean of control as well as the recording method and the reaction plan in case of non-compliance.
- The planning of the risk analysis

### 7.2 Processes related to the customers

#### 7.2.1 Determination of the products requirements

The business sub-process of the customer-related process PGQL034 describes the activities in order to prepare, review, approve an offer, as well as to identify and review the requirements related to the products. The PSR process liaises and formalizes the expression of the customer need and of Saft technical response integrating the product requirements.
As part of the medical activities, specific rules are defined regarding the requirements review related to the IEC 60601 (design rules for the medical devices batteries)

#### 7.2.2 Product requirements review

The "Order processing, tracking and delivery" process PGQL025 includes the review of the customer requirements, particularly those related to the products.

A review of the customer requirements is systematically carried out conducted for each order or contract in order to:

- Ensure the adequacy of the order with the commercial offer
- Ensure that the product requested is available for sale (defined and marketable product)
- Ensure that the proposed product meets all the specified requirements including the legal and regulatory requirements
- Measure the possible discrepancies and remove any ambiguity regarding the needs of collaboration with the customer
- Ensure that the division is able to meet all the requirements: product, deadlines, acceptance tests, accompanying documents,...
- The implementation of the log book in accordance with the POP 47190 (traceability, configuration management, validation Quality validation)

The existing contract or order amendments are treated the same way.

#### 7.2.3 Communication with the customer

The process related to the customers PGQL034 describes the measures taken towards these issues.
As part of the project activities regarding development of new batteries, regular interactions are organized between Saft project teams and the customers. They foster the development of customer relationship, the efficiency in technical decisions and the transparency of the project situation particularly in case of difficulties or potential impacts on the deadlines.
Regarding the technical solutions proposed by Saft, product information is available on Saft Website.
For the Civil Electronics Division, the customers' feedbacks, including their claims, are taken into account through « customer claims» process (PGQL026).
In addition, a warning document containing information about the proper use of the device, its modification and end of life will be associated to the simplified battery sheet at each order of a battery for medical devices.

### 7.3 Design and/or development

#### 7.3.1 Planning of the design and/or development process(es)

The battery development process PGQL035 defines the modalities for the planning and management of the design activities and the qualification of the batteries.

#### 7.3.2 Design and development inputs

The design input data are identified, documented and reviewed during the initial phase of the planning.

For the new medical projects and according to the complexity of the battery, a project risk analysis is conducted and thus allows deciding on the necessity to conduct specific risk analyses such as AMDEC product, process. Indeed, Saft uses design rules that have been updated on the basis of feedback and predefined products/process control plans. However, to better understand the conditions of use and the environment of the battery, an additional risk analysis is conducted by referring to the annex E2 of the ISO 14971:2007 standard.

All the inputs elements related to the design and development are kept.

### 7.3.3 Design and development outputs

The design output data are formalized and allows to:

- Check the adequacy with the design inputs requirements.
- Define the documents and information required by the purchasing department and the production, including the control and acceptance criteria of the products.
- Specify the optimum conditions of use and safety of the products.
- Specify the specific measures to be implemented in terms of control of the products and process characteristics, as well as the related records (product/process control plan)
- Identify the critical elements (see definitions hereunder).

*Critical elements*: *All the elements having a significant effect on the product realization and use, including safety, performance, space occupancy, interchangeability and the function, producibility, service lifetime… (ex: functions, parts, software, characteristics, processes)*

All the output elements related to the design and development are kept.

Note: These elements may include the specifications, manufacturing procedures, engineering drawings, design and development records and the battery information sheet.

### 7.3.4 Design and development review

The development is organized in phases. The transition from one phase to another is formalized by a review (milestone) at the end of the phase.
The application of these phases and associated reviews can be modulated depending on the project complexity.
The records related to the reviews are kept.

### 7.3.5 Design and development verification

The design verification is performed at each phase of the design to ensure that the output data of that phase meet the input specifications. The design verification is recorded.

### 7.3.6 Design and development validation

The design validation is performed to ensure that the product complies with the requirements and/or user specifications. Specific testing programs are planned for this purpose. The validation is normally performed on the finished product but can be performed upstream, if appropriate. The design validation is recorded.

Note: The batteries for medical devices manufactured by Saft are not affected by the regulations requiring clinical assessments.

### 7.3.7 Control of the design and development modifications

Any change in the design during the project is integrated into the ongoing project, under the responsibility of technical function or of the project manager. The impacts of this modification on the project progress will be analyzed and the potential differences justified during the review.

Any change in the design during the serial life of a marketed product, will be managed according to the terms of the procedure POP 47135 "Management of the technical developments". The changes in the design or the modification are identified, documented, reviewed, approved and recorded.
In general, all the modifications considered as major (examples: impacting the product interchangeability, the interface with the customer's device,…) will be subject to a validation request from the client concerned. Therefore, a RFA (Request For Approval) will be issued to the customer for approval before modification.

## 7.4 Purchasing

### 7.4.1 Purchasing process

This process is described in the procedure PGQL029:

The measures implemented are based on:

- The method for the evaluation and selection of the new suppliers is based on a quality survey and a risk assessment. This assessment leads to the introduction of new suppliers in the Approved Suppliers List (ASL) of the Division. This list is consolidated at SAFT. It is registered.
- The verification of the conformity of the product purchased regarding to the purchasing requirements specified.
- The qualification of the supplier product/process in partnership with Saft technical services is based on audits and technical validation of the product.
- The monitoring of the supplier by a quotation taking into account the quality criteria of the products supplied (through Saft inputs control results and the production line feedbacks), and the deadline. The results are recorded. These results are communicated to the suppliers as part of the customer/supplier meetings.
  A monthly meeting deals with the underperforming suppliers "bottom 15" and lead to the implementation of specific actions to redress the situation and improve the performance.

### 7.4.2 Information related to the purchases

They are provided by the purchase order accompanied, if necessary, by technical documents such as drawings or specifications. The suppliers accuse receipt of the technical documents received.

Saft requirements in terms of relationship with the suppliers are defined in the "Requirements and Supplier relationship" procedure POP47069.

The relevant documents related to the purchases are kept.

### 7.4.3 Verification of the purchased product

The verification of the purchased product is carried out by the supplier and/or by the Division incoming inspection. The nature and the extent of the controls depends on the product, the measurement of the

supplier's quality performance and the implementation of the "Product Quality Assurance" with the supplier (POP 47075).

Where required by the contract, measures are taken to allow the customer or his representative to carry out the verifications in the supplier's premises.

The "Supply" is integrated into the "Production" process described in the PGQL 028.

## 7.5 Production and preparation of the department

### 7.5.1 Control and preparation of the department and production

#### 7.5.1.1 General requirements

The production preparation activities are described in the "Sales forecasts and Production plan" process (PGQL 024) which helps establishing the production plans according to the commercial needs.

The activities aimed at controlling the production steps are described in the "Production" process (PGQL028).

This process describes the different ways to obtain controlled production conditions, particularly regarding:

- The equipement (machines)
- The staff (workforce)
- The purchased components (matierial)
- The industrial documentation related to the product, particularly the records required (methods)
- The work environment
- The implementation of labeling and packaging operations

The latter requirement, specific to the medical devices, provides the traceability per batch meeting the requirements of the paragraph 7.5.3.

#### 7.5.1.2 Control of the production and of the preparation of the department - Specific requirements

##### 7.5.1.2.1 Product cleanliness and control of the contamination

The requirements about the cleanliness of the supplied products are expressed in the instruction sheets, which are available on the concerned stations. There is no special requirement regarding the product decontamination before its delivery. If a customer expresses a specific need on that matter, it will be addressed as part of the project risk analysis and specifically treated (specific requirements).

##### 7.5.1.2.2 Installation activities

The installation of Saft products is done by the customer. In order to create the best conditions, specific instructions are provided by Saft, for the integration of the battery in its system.

##### 7.5.1.2.3 Related services

When associated services are specified in the contract, they are reviewed, analyzed and treated through the same completion processes as those related to the products.

These services can be classified in the following categories:

- Documentation
- Studies
- Commissioning
- Customer training
- Waste, recovery
- Supply of raw materials and spare parts
- Maintenance
- Repair

Depending on the case, Saft Poitiers establishes documented procedures for the implementation of the service, as well as the verification of their compliance with the requirements.

The records of the related services and services carried out by Saft are kept.

#### 7.5.1.3 Particular requirements for sterile medical devices

Not applicable to the batteries. The sterilization procedure (only performed according to the classification of the device) is carried out by the customer.

### 7.5.2 Validation of the production processes

#### 7.5.2.1 General requirements

The new processes, including the special processes or equipment are subjected to a formalized validation before commissioning. It includes the industrial documentation, staff training, compliance with the standards (Health/Safety/Environment included), adequacy with the technical objectives and maintenance plan (see procedure POP47048 "Process control").
The process of production validation first requires the production of pre-series, in order to validate all the measures implemented to ensure the product compliance. This phase also allows to train the staff for a better understanding of the work instructions and collect, if need be, the areas for improvement. The entire process is described in the PGQL 035.

Any process or equipment modification requires the implementation of all or part of the development approach.

The records of the validation results are kept.

#### 7.5.2.2 Particular requirements for sterile medical devices

Not applicable. This section does not apply to the Medical devices produced by Saft as they are not sterilized.

### 7.5.3 Identification and traceability

#### 7.5.3.1 Identification

Any item or product has an "identification system" used as means of recognition and comprising at least of the two following information:

- An item code: numeric or alphanumeric
- A clear alphabetical designation.

Additional information such as the batch N°, the reference of the technical specification or of the associated plan etc..., are added according to the customer's needs.

To ensure the continuity of this identification, the "identification system" selected appears "clearly" on the product itself, or its packaging, or on the location of its storage or use site and appears in each document or record attached to the item or product movements.

Moreover, the finished products (finished cells or battery assembly) as well as the bare cells are, unless required otherwise, unitarily identified by their batch n° or manufacturing date.

Measures are taken to identify the critical components original batch and ensure the response to the anomalies from downstream to upstream (to identify the suspect components batch in case of anomaly on the final product) but also upstream to downstream (to identify the batches of products contaminated by a defective component).

The PGQ 46013 describes the applicable measures in case of anomaly.

#### 7.5.3.2 Traceability

##### 7.5.3.2.1 Generalities

The traceability requirements are implemented through a log book which allows a better traceability of "at risk" components and a better manufacturing monitoring according to the POP 47190.

##### 7.5.3.2.2 Particular requirements for the active implantable devices and the implantable medical devices

Not applicable. Saft does not produce such devices.

#### 7.5.3.3 Identification of the product condition

The identification of the product condition is maintained at each step of the production, storage, installation and related services, and ensures that only a product having successfully passed the controls and tests required is deliverable, usable by the customer.

The operators perform a self-inspection at each step of the production and additional controls according to the instructions defined in the work instruction. The log book provides a complete traceability of the manufacturing operations and controls.

A certificate of conformity with the ISO13485 standard is established at each end of production and is validated by the Quality Department.

#### 7.5.4 Customer property

The procedure PGQL 007 describes the measures taken to identify, protect and check the products or equipment owned by the customers, for the Batteries Unit.

#### 7.5.5 Product preservation

The methods used for the identification, handling, packaging, storage and protection of the components and products during their production are described in the procedure PGQL015.

Measures are taken for the management of the controlled conservation products (specific storage conditions and/or time-limited).

The specific product management allows their use or shipping under the FIFO (First In, First Out) method.

The specific storage conditions are controlled and recorded.

### 7.6 Control of the monitoring and measurement devices

The rules related to the control of the monitoring and measuring devices are described in the procedure PGQ 46011.

The measuring equipment is identified and subjected to periodic verification. The validity date of the verification appears on each equipment.

After verification, if the equipment turns out to be **"**defective**"**, an investigation is conducted to determine the impact of the products manufactured and, potentially, delivered.

These facilities are listed in a computer database that allows the management of the equipment.

The controls, verifications and calibrations are performed in an air-conditioned room, where the temperature and humidity are controlled.

The verification findings are archived records.

## 8. Measurement, analyses and improvement

### 8.1 Generalities

The monitoring, measurement, analysis and improvement processes implemented are described in the procedure PGQL032.

### 8.2 Monitoring and measurement

#### 8.2.1 Customer feedbacks

The "data and analyses related to the customers" sub-process describes the methods used to collect the customer satisfaction elements, particularly:

- The processing for the product returns and the customer claims according to the PGQL026,
- The assessment of Saft's performance provided by some customers,
- The external audits carried out by the customers or stakeholders,
- The customer satisfation surveys,

This information is analyzed during the Management Review in order to establish improvement action plans.

Note: Saft is not responsible for the medical device vigilance statements to the ANSM (French Agency for the Safety of Health Products) in case of defective products. The customer who integrates the battery into his system will have to undertake steps with the ANSM, if need be.

#### 8.2.2 Internal audit

An annual internal audit program is established by the Quality, Health-Safety and Environment functions to ensure the QSE Management system compliance and effectiveness. It covers the scope of the activity and includes system and field audits (implementation process). It can be modified, under the Quality Manager responsibility, to reflect the importance of the activities to be audited and the results of the previous audits. The program specifies the team and object of the audit.

Only the authorized and qualified auditors may conduct the audits in accordance with the ISO13485 standard (compliance with the standard).

In case of discrepancies, the managers of the departments audited shall analyze the causes, define and carry out corrective actions. The effectiveness of these actions is verified or evaluated. The corrective actions evolution defined during the audits is examined during the Management Reviews (see process description §8.1).

The audit reports are recorded and managed by the Quality System function.

The activities related to internal audits are described in the **"**Internal audits management**"** procedure PGQ 46017-16 also called **"**Quality Management and continuous improvement**"** in the PGQL032.

#### 8.2.3 Processes monitoring and measurement

For each process, a supervisor is designated. He is responsible for the proper functioning and the improvement of the process. To do so, he uses indicators defined in line with the policy and the quality safety environment objectives. They can evolve according to the needs.

These indicators are examined during the Management Reviews in order to ensure the effectiveness of the processes and their improvement.

#### 8.2.4 Products monitoring and measurement

##### 8.2.4.1 General requirements

The characteristics of the product are monitored, measured and recorded during all the manufacturing cycle, particularly:

- Upon receipt of the components purchased: the components purchased cannot be used before the verification of their compliance according to the "Incoming Inspection Compliance Verification" POP 47124. This verification is performed by the incoming inspection department, or by the supplier as part of the P.Q.A. (Product Quality Assurance). The P.Q.A. process is subject to a procedure defined in the POP47075.
- During the production: the products are controlled as provided in the work instruction POP 47106.
- During the final inspection: according to the provisions of the procedure POP 47101.

The different records are managed according to the provisions of the paragraph 4.2.4.

The products, which have not been declared compliant, are not usable.

#### 8.2.4.2 Particular requirements for the active implantable devices and the implantable devices

Saft does not produce such devices and is therefore not concerned by that parte.

### 8.3 Control of the non-compliant product

The operations and responsibilities related to the control of the non-compliant product are detailed in the "Control of the non-compliance" procedure PGQ46013.

When a non-compliant product is detected, it is identified and isolated to prevent any risk of use or inadvertent shipment. The non-compliant product can be:

- Reworked in production according to the instructions predefined and validated
- Accepted by derogation with or without rework
- Downgraded for another use
- Disposed

If defined in the contract or when the product has been design by the customer, his notice is required for any acceptance by derogation with or without modification.

If a non-compliance is detected by Saft, on products already delivered, a study is conducted to define the criticality of the non-compliance with respect to the customer requirements. If the impact is important, the customer is informed about the nature of the defect by the sales management and the products delivered can be recalled. Then, they are treated as customer returns (repaired or replaced).

As part of an operation of rework, it is described in a temporary or final instruction subjected to the same authorization and approval procedure. The determination of the rework potential negative effects is made and documented.

An analysis is performed to identify the causes. This analysis allows defining the appropriate part of the system on which the actions are conducted. The plan developed takes into account the problem solving but also the preventive measures to avoid any recurrence.

The records related to the non-compliance and its processing are managed and kept. (cf. § 4.2.4).

### 8.4 Data analysis

As decribed in paragraphs 8.1 and 8.2, the data listed hereunder are collected and analyzed. They are presented during the Management review in order to evaluate QSE system effectiveness.

- Related to the products
- Related to the processes
- Related to the audit results
- Related to the customers and stakeholders
- Related to the Health-Safety Environment performance

The records of the data analysis results must be kept (see § 4.2.4.)

## 8.5 Improvement

### 8.5.1 Generalities

During the Management Reviews, the consideration of various issues such as the QSE policy, the related objectives, the results of internal and external audits, the data analysis, the preventive and corrective actions, the proper functioning of the processes and the related indicators allow the Division Management to make decisions about the improvement actions and to evaluate the integrated management system effectiveness.

Moreover, the continuous improvement of the Division efficiency relies heavily on the company project called "World Class". An overall assessment of the division is carried out every three years and an improvement plan is established to meet the objectives adopted.

The Civil Electronics Division is particularly committed to develop and strengthen its know-how in the following fields:

- Safety
- Quality
- Cost
- Deadlines
- Staff involvement
- Environment

The main actions carried out to support this approach are:

- Structured working groups: PDCA, Kaizen
- The development and the quality control: F.M.E.C.A., problem solving (8D), 6 sigma,…
- The control and the improvement of the performance: TPM, SMED, Lean,…
- The flow management: Kanban, VSM, Leadtimes,…
- The 5S, the visual management, …
- The skills development through training modules such as « Lithium-Pro »,…

The selection and measurement of the efficiencies is done through industrial performance indicators.

### 8.5.2 Corrective action

The procedure PGQL 032 **"**Quality management process and continuous improvement**"** deals with the steps taken to initiate and handle a preventive action.

Corrective actions are initiated, for example, in case of return or customer claim, in case of major problems in production,…. The corrective action processing is based on:

- The determination of the causes of the non-compliance,
- The implementation of corrective actions,
- The measurement of the effectiveness of the actions carried out through the indicators and internal audits,
- The actions standardization.

### 8.5.3 Preventive action

The procedure PGQL 032 **"**Quality management process and continuous improvement**"** deals with the steps taken to initiate and handle a preventive action.

The preventive actions can arise from:

- The work carried out during the products design and development,
- The F.M.E.C.A. analysis (Failure mode effects and criticality analysis) performed on products, equipment and processes,
- Operational security studies,
- The **"**act**"** phase (standardization and generalization) of the continuous improvement groups
- Customer claims processing,…