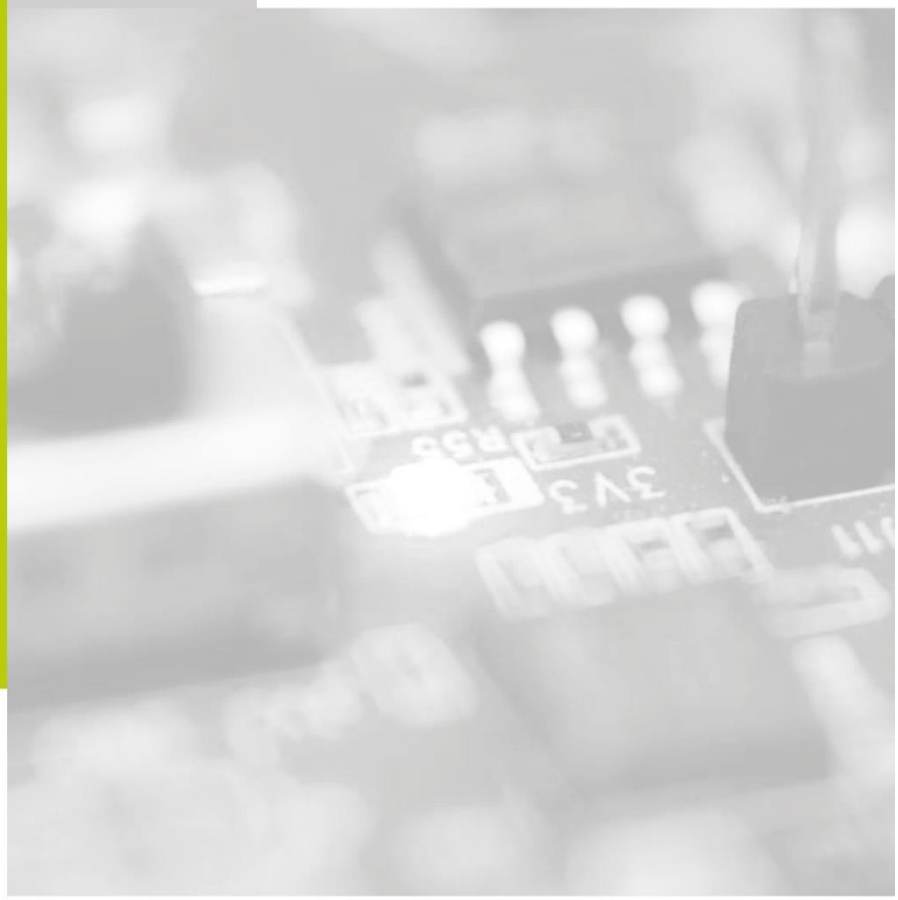
tuomi



QUALITY MANUAL

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1. PREFACE

tuomi has implemented the Quality Management System EN ISO 13485:2016 using a process approach. The Quality Management System ensures the implementation of consistent quality throughout all processes with the objective to continuously measure, evaluate and improve these processes.

Working in a field in which standards, guidelines and regulations are constantly changing, tuomi ensures that the Quality Management System is continuously updated taking these changes into account.

This Quality Manual is written with the utmost care, to make certain that everyone in the company understands tuomi's Quality Management System and tuomi's commitment to quality.

Company: tuomi S.A

Name: Arja Roos

Position: Managing Director

Place: Mertert

Date: February 26 2020

2. GENERAL

2.1 PURPOSE

This Quality Manual describes the Quality Management System (QMS) of tuomi demonstrating the ability to provide products that consistently meet client needs and regulatory requirements.

The QMS is set up according to the requirements of the international standard EN ISO 13485:2016.

The purpose of this Quality Manual is to define the scope of tuomi's QMS, to document and to refer to the procedures of the QMS, to define authorities and responsibilities of the management and other personnel involved in the operation of the QMS, and to provide a general description and interaction of the processes of the QMS.

Another purpose of this Quality Manual is to present the QMS to economic operators, regulators and other external parties, and to inform them about specific controls implemented at tuomi to assure the quality of the products.

2.2 SCOPE AND APPLICATION

This Quality Manual documents tuomi´s quality policy and objectives. It provides a description of how the quality policy is maintained during day-to-day operations.

This Quality Manual is a permanent reference to the implementation, updating and improvement of the QMS. Tuomi's scope regarding EN ISO 13485:2016 /MDR is:

- tuomi develops software on behalf of its clients
- tuomi programs software according to client´s requirements

- tuomi has integrated its own software development processes that are indispensable to provide services in the field of software development
- tuomi performs servicing and maintenance activities on behalf of its clients
- tuomi is a service provider: tuomi sells software development services. These services include the following features:
    - design according to client requirements
    - implementation of the design in software
    - verification of developed software
- tuomi does not perform any marketing and sales activities that concern products developed on behalf of its clients
- tuomi buys hardware solely to be used in the software development environment

Tuomi is not an importer, distributor or manufacturer but a software development service provider, including software for medical devices according to MDR.

Tuomi adheres to the standards and regulations of product safety and performance what regards the role of a critical supplier

- tuomi maintains a Quality Management System
- tuomi maintains a Risk Management System
- tuomi maintains a Technical Documentation
- tuomi takes appropriate actions in case of Complaints, Incidents or Recalls
- tuomi takes Corrective and Preventive Actions in order to improve the processes and products and to eliminate undesirable effects

2.3 STANDARDS AND REGULATIONS

The following regulations and standards are applicable:

- Medical Device Regulation 2017/745/EU
- EN ISO 13485:2016 Medical devices – Quality Management Systems – Requirements for regulatory purposes
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- EN 62304:2006 + Cor.:2008 + A1:2015 Medical device software – Software life-cycle processes
- IEC 62366-1:2015 + AC:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 82304-1 Health software – Part 1: General requirements for product safety

2.4 ACRONYMS

MDR : Medical Device Regulation 2017/745/EU

NFC: Near Field Communication

QA/RA: Quality Assurance/Quality Affairs

QMS: Quality Management System

SOP: Standard Operating Procedure

UI: User Interface

3. COMPANY INFORMATION

3.1 COMPANY ADDRESS

TUOMI S.A.

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3.2 COMPANY BACKGROUND

tuomi is a well-established systems house based in Luxembourg specializing in software development, IT applications, network technology and IT security. Since the company was founded in 1995, tuomi has developed from IT service providers to specialists in technology of data security, data protection, cloud computing and experts in the design and implementation of applications in the field of NFC (Near-Field-Communication) technology and mobile application development.

3.3 MANAGEMENT COMMITMENT

The Managing Director and QA/RA Manager of tuomi are responsible for the development, implementation, maintenance and effectiveness of the Quality Management System.

3.4 CUSTOMER FOCUS

tuomi focuses on high quality of its services and trouble-free communication between tuomi and the client. The client inquiries and offers are elaborated accurately and prompt. tuomi accepts client orders only if tuomi can meet client´s needs. The orders are fulfilled with utmost care and within the set time lines and according to all regulatory requirements. The loyalty of longtime clients to the company demonstrates the client satisfaction of tuomi services.

3.5 MISSION STATEMENT

Right from the start, tuomi has focused on the development and power of new technologies. Tuomi has the set goal to develop and deliver state of the art products and solutions that are carefully elaborated, innovative, functional, and user-friendly. tuomi maintains high security and quality standards for the products and solutions. The data security and data protection has always been one of the most important tasks for tuomi. tuomi safeguards its data from unauthorized internal and external access and relies on safe internal and external communication. The data security - including data encryption, backups, data recovery- have always played an important role in tuomi´s company policy and has been one of the core business activities for tuomi.

3.6 QUALITY POLICY

tuomi aims to deliver consistent quality software solutions by continuously evaluating and improving clients' total experience with the company. tuomi diligently strives for excellence in client´s satisfaction by meeting the expectations of each client.

Quality is an integral part of our business objectives and the high quality is guaranteed by laying down a management system of established processes and objectives within the company. We are committed to comply with (regulatory) requirements and to maintain the effectiveness of the quality management system.

The requirements as stated in EN ISO 13485:2016 provide the framework for the QMS. tuomi is committed to regulatory requirements being determined and met. The quality policy is regularly reviewed for continuing suitability in the Management Review.

tuomi maintains product conformance via partnerships with approved suppliers who are a key element in our ability to deliver safe products to the medical community.

3.7 QUALITY OBJECTIVES

Quality objectives are defined to meet applicable regulatory requirements and requirements for products that are measurable and consistent with the quality policy.

In general, the objective of tuomi operations is to run efficiently, provide consistent, high-quality products and services, and continuously improve their client's experience. The main objective of tuomi is the operational efficiency. Tuomi aims to deliver products and services while ensuring high quality of products, service, and support.

To achieve the set objectives, it is necessary to ensure conformity of products and QMS and review the suitability, adequacy, and effectiveness of the quality objectives.

tuomi determines appropriate methods, including statistical techniques, and the extent of their use. The quality objectives are reviewed on a regular basis.

3.8 RESPONSIBILITY AND AUTHORITY

Personnel are given the authority and responsibility to carry out their specific tasks. All personnel are expected to maintain the specified standards for all activities affecting quality and share the responsibility of identifying non-conformities or possible areas for improvement. The responsibility for each function is illustrated in tuomi's organisation chart.

3.9 MANAGEMENT REPRESENTATIVE

The Quality Management System Representative (QMS-Representative (QA/RA Manager)) is responsible for establishing and enforcing the QMS. In addition, the QMS-Representative is responsible for reporting on the effectiveness of the QMS and promoting awareness of applicable regulatory requirements and QMS requirements at the organisation.

3.10 INTERNAL COMMUNICATION

Management ensures that appropriate communication processes are established within the organisation and to assure effective communication on all levels within the organisation with regards to the QMS and its effectiveness.

Training on QMS is updated on a regular basis, as applicable. New employees are introduced to the QMS including the quality policy.

4. QUALITY MANAGEMENT SYSTEM

The QMS of tuomi is scaled according to the size of the organisation and adopted to the type of activities, the complexity of processes and their interactions, and the competence of personnel, applying a risk-based approach.

A risk-based approach is used to control the processes needed for the QMS. For all QMS processes, risks related to those processes as well as implemented control measures are identified and documented.