QUALITY PROCEDURES MANUAL

ISO 13485:2016

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QUALITY PROCEDURES MANUAL

MANUAL IDENTIFICATION

Copy Number 1 of 1

Issued to: Medical Devices Technology International Ltd

Title Version 1.28b

Signed: ..... Adam Law **.....**

Management Representative/Quality Manager

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REVISION AND AMENDMENT REGISTER

DATE	PAGE NUMBER	PROCEDURE NUMBER	REVISION DETAILS	ISSUE NUMBER
07.11.06	9	Policy	Update the policy to ISO13485:2003	1.1
07.12.06	16-17	Quality Plan	Update to include procedure for customer notification	1.2
15.01.07	63 and 53		Update details on nonconforming products and Traceability	1.3
	17-19	Quality Plan	Add customer and product survey details	1.3
02.07.07	11		Update of Organogram	1.4
04.12.07	11		Update of Organogram	1.5
04.12.07	18	Quality Plan	Add regulatory documents to plan under section 2 and addition of Artwork and Design under section 3 Add full clinical trials/testing and published journal document	1.5
04.12.07	1.8	Quality Plan	Section 8 – despatch, all orders double counted, and quality control sticker applied	1.5
04..12.07	P8	Profile	Update profile and include Mission and Vision statement	
04.12.07	5.6.1	Management Responsibility	Change of time for management reviews	
04.12.07	4.2.1	QMS	Technical files documentation and regulatory issues	1.5
04.12.07	7.3	Product Realisation	Deign & development	1.5
04.12.07	7.5.2	Product Realisation	Valid of inspection processes	1.5
04.12.07	7.4 (2)	Purchasing	Critical suppliers	1.5
04.06.08		11	Update of Organogram	1.6
04.06.08	34	5.5	Changes to participants at meetings	1.6
02.10.09		9	Change from class 1 to 'medical device products'	1.7
02.10.09		11	Update of Organogram	1.7
02.10.09	4.1	19	Add in Pre- commercialisation stage	1.7
02.10.09	1	11	Add in services within scope	1.7
05.05.10		n/a	Changed 9001:2000 to new std 9001:2008	1.8
05.05.10		P8	Update profile	1.8
05.05.10		P10	Quality policy revision to reflect std change	1.8

05.05.10 **30.09.10**	 **5.6.1.3/7.4.3.1**	**P11** **P37P52**	**Organisation chart changes** **add of appendix 2 re suppliers**	**1.8** **1.9**
30.09.10	**5.6.1.3/7.4.3.1**	**P37/P52**	All new suppliers have to complete the Suppliers Evaluation Questionnaire (Appendix 3)	**1.9**
30.09.10		**Throughout**	**Updated throughout to add ISO 13485:2003 requirements**	**1.9**
30.09.10	**4**	**P17-19**	**Removal of Quality Plan, now found in Appendix 1**	**1.9**
04.10.10	**7.5.3**	**P54**	Process Maps are available in the blue Process folder for: 1 Batch Control 2 Checking and acting on Medical device alerts for MHRA, FDA & Med safe	**1.9**
04.10.10	**7.5.3**	**P54**	Vigilance and Post market surveillance reporting for adverse Incidents and Near Accidents for EEC, US and New Zealand are found in Section 7 of the Technical Folder	**1.9**
04.10.10		**P12**	**Update of Organogram**	**1.9**
04.10.10	**7.3.7**	**P50**	**Appendix 4 note – design/review sign off**	**1.9**
17.11.10			**Overall review of all clauses to reflect organisation and revision of audit planning**	**1.10**
28.02.11		**Throughout**	**Updated throughout to add ISO 13485:2003 requirements**	**1.11**
15.04.12 **17.1.13** **12.12.13** **03.11.15** **03.11.15** **01.11.15** **03.12.15** **01.01.16** **03.04.16** **20.06.16** **15.04.18**	 **P49, P50** **P12** **P11** **P47** **P53** **P12** **P11** **P51** 	**Throughout** **Throughout** **Section 7.2.3** **Section 1** **Section 7.2** **Section 7.4.1** **Section 1** **Section 7.4.1** **Through out**	**Updated throughout to reflect changes with Directive 2007/47/EC and in responsibility and improvement to processes** **Updated throughout to reflect change of Standard name from 13485:2003 to 13485:2012** **Currently using Sage and not ACT** **Revision of Scope** **Update to organisational structure** **Review and change point 7 and 8** **Procedure for re-evaluation of critical suppliers' criteria added** **Updated scope** **Updated organisational chart** **Addition of compliance to ETI base code** **Updated throughout to add ISO**	**1.12** **1.13** **1.13** **1.14** **1.15** **1.16** **1.17** **1.18** **1.19** **1.20** **1.21**

			13485:2016 requirements v1.17	
3.1.19	52-53	6.4.1, 6.4.2	Include Pest Control provision	1.22
20.4.19		Through out	Updated throughout to ISO 13485:2016 requirements v1.18	1.23
20.4.21		Through out to reflect requirements of MDR	Updated throughout to ISO 13485:2016 requirements v1.19 and change in scope with removal of Uflow meter from market	1.24
20.12.21	85	8.2.4	Added impartiality to audit away from activity owner	1.25
20.12.21	83	8.2.3	Change from MEDDEV 2.12.-1 Rev 8 to MDR 2017/745 reflect 'other incident' at 15 days.	1.26
17.02.22	31	4.2.3	Inclusion of medical device files should be established in accordance with MDR (EU) 2017/745 Annex II	1.27
22.06.22	17	4.2.2	List of non-applications/exclusions	1.28
22.06.22	12	4.2.2	Process sequence and interactions	1.28
23.06.22	13	4.2.2	Documentation Hierarchy	1.28
23.06.22			Inclusion of Appendices Update	1.28
20.04.23	61	7.2.3	Remove the mention of Trade Box and replace with NETIX	1.28a
20.04.23	77	7.5.9.1	Vigilance and Post market surveillance reporting for adverse Incidents and Near Accidents for EEC, US and New Zealand is updated to reflect Section 6 of each product technical folder.	1.28a
09/12/24	12	Section 1	Revision of Scope	1.28b

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FOREWORD

This Quality Procedures Manual is the means by which MDTi (the 'Organization') satisfies the requirements of its customers, particularly with regard to management responsibility.

The Organization is obliged to ensure that its Quality Policy is fully and completely understood by its employees, and that its procedures are implemented and maintained at all times. This Quality Procedures Manual is in accordance with the requirements of **BS EN ISO 13485:2016**. All the components of the Quality Management System shall be periodically and systematically reviewed by both internal and external Quality Audit procedures.

The Management Representative/Quality Manager, appointed by the Organization, is responsible for the control of all matters relating to the implementation of these procedures.

The assurance of quality is fundamental to all the work undertaken by the Organization. All personnel at every level in the Organization's structure shall practice the procedures established.

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PROFILE

MDTi is a private company that works in collaboration with strategic partners in the healthcare industry.

The company's aim is to bring to market innovative medical devices that are easily understood and uncomplicated but provide real benefits to practitioners and patients to make health care more efficient and safer.

MDTi (www.mdti.co.uk) was founded in October 2003 to realize a business opportunity that the 2001 NHS legislation presented. MDTi's modus operandi is to license in the Intellectual Property (IP) within Class 1 Medical Devices (effectively low-tech devices) and then bring to market product based on the underlying IP. Prior to licensing, the IP has been evaluated both within and outside the NHS as suitable for profitable commercial exploitation.

The company began formal trading in March 2004 after securing initial funding from private sources to undertake; developing a robust business strategy, positioning the business as the preferred conduit by the NHS for its Class 1 product IP, establishing an operational infrastructure and to launch its first licensed NHS product to market (i.e. Hook-It® range of IV/fluid hooks).

MDTi has subsequently developed to the point where it currently has thirteen exclusive world-wide license agreements in place with the NHS and is currently in negotiation on a further four products, in addition the company has successfully achieved NHS National Purchasing Contracts on all eight to date. MDTi is the first company from a start-up position to have achieved such contract status from any public sector procurement authority after trading for a period of less than three years.

In addition and in a short timeframe, the company has successfully negotiated national contracts to supply all Spire (previously Bupa) hospitals on two of its products (the Hook-It® range of IV/fluid hooks and the Ortho-Glide® a lower leg exerciser), and is working towards similar arrangements with BMI and the Ramsay healthcare (formerly Capio Hospital) group. It also supplies to Amazon across Europe, USA and Australia under FBA (Fulfilled by Amazon) whilst merchant fulfil under over Amazon territorial platforms.

With the fundamental shift in the UK, following BREXIT, and International healthcare service delivery from Secondary to Primary care in an attempt to save money and to empower healthcare consumers to be more directly responsible for their treatment regimes, the medical device market is already witnessing the inevitable migration from high value Hi-tech devices to more easily understood, cost-effective and patient-useable Low-tech devices.

MDTI is ostensibly a Business Development and Sales and Marketing organization focused on the licensing in of medical device product ideas. To date all Intellectual Property has emanated from within the NHS and as such is synonymous with quality, this linkage means MDTi is able to command a high level of acceptance for both the products that it brings to market and its brand (effectively both carrying an NHS "endorsement") from a wide variety of healthcare practitioners

who are the drivers for take-up by the healthcare consumer.

The MDTi proposition generates revenue streams from increasing numbers of NHS-derived products by licensing in the IP in such products then catalyzing the commercialization process to get product to market and generate sales, the costs of filing and protecting IP being borne by the NHS. The approach taken provides a financial return to the NHS through the payment by MDTi of sales-based royalties back to the NHS and in so doing creates a strong barrier to entry against other suppliers that may wish to offer competitive products and a highly reputable platform for product pull into private healthcare providers.

As the MDTi brand grows, licensing opportunities from outside the NHS will undoubtedly arise but current thinking is that all licensed IP should have been introduced via the NHS.

MISSION STATEMENT

We are here day by day to deliver the best products and services that improves the lives of Clinicians and Patients.

MDTI'S VISION

To be the leader of Innovative Medical Devices that emanate from healthcare professionals that are easily understood and that are uncomplicated.

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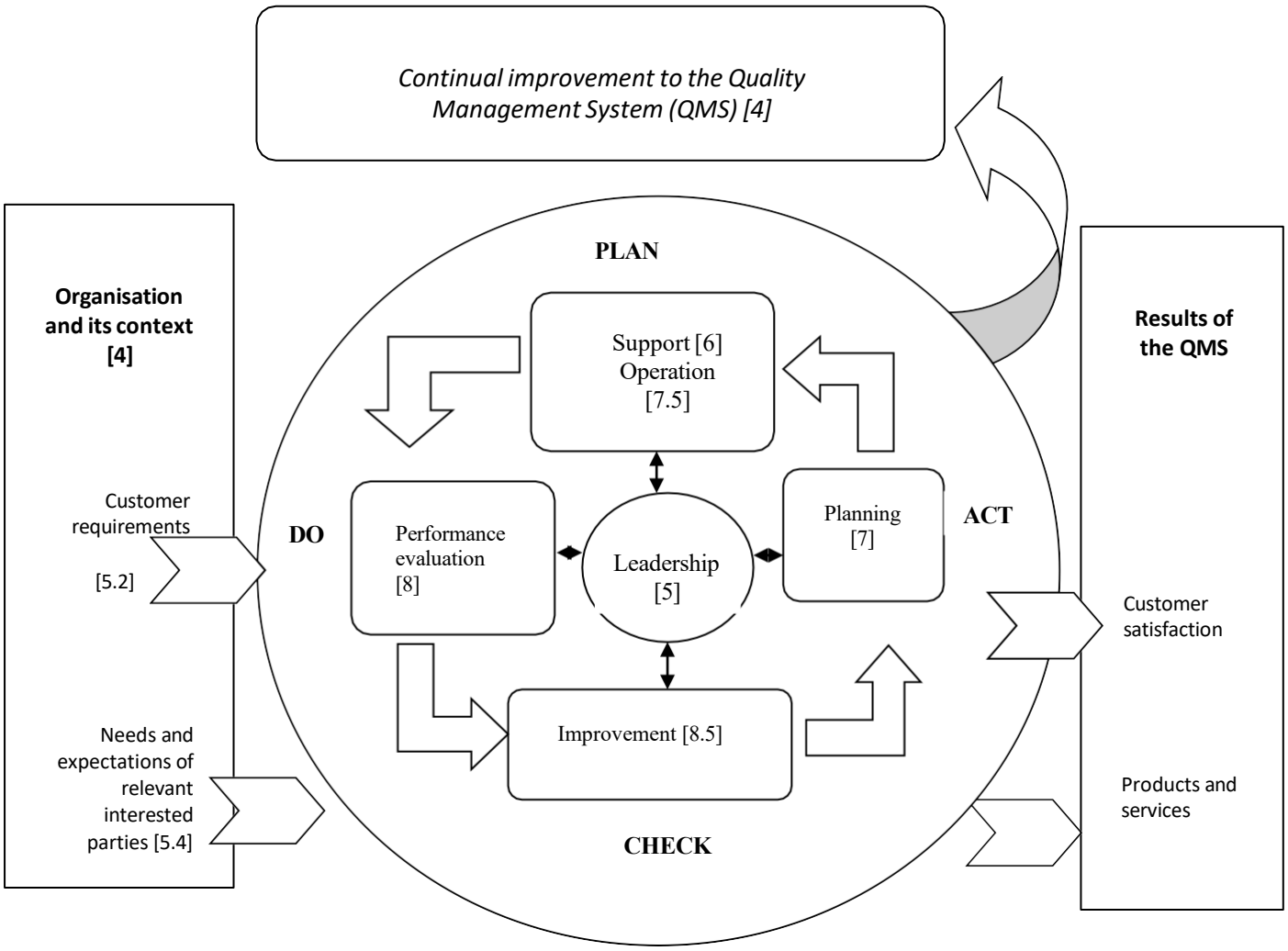
INTRODUCTION



Note: Numbers in brackets refer to the clauses in the international standard

FIGURE 1 – PDCA model applied to QMS processes

Plan (establish the QMS)	Establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, identify and address risks and opportunities.
Do (implement and operate the QMS)	Implement and operate what was planned; the QMS policy, controls, processes and procedures.
Check (monitor and review the QMS)	Assess and, where applicable, measure process performance against QMS policy, objectives and practical experience and report the results at management review.
Act (maintain and improve the QMS)	Take corrective and preventive actions, based on the results of the internal QMS audit and management review or other relevant information, to achieve continual improvement performance of the QMS.

Note: To conform International Standards, MDTi is required to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the QMS.

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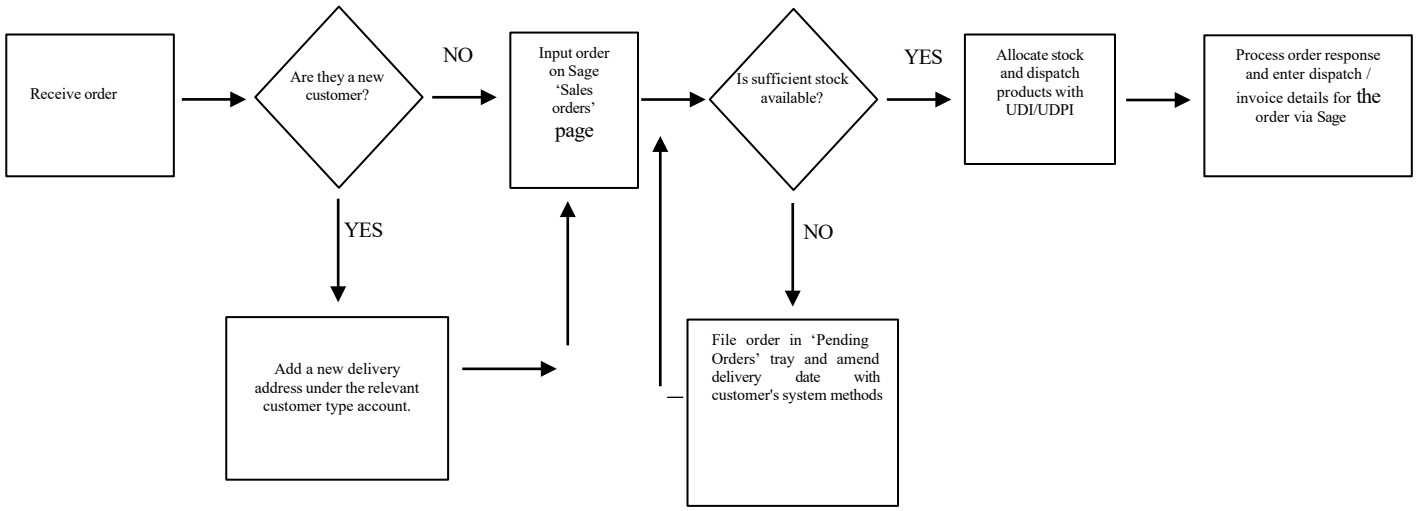
PROCESS SEQUENCES AND INTERACTIONS



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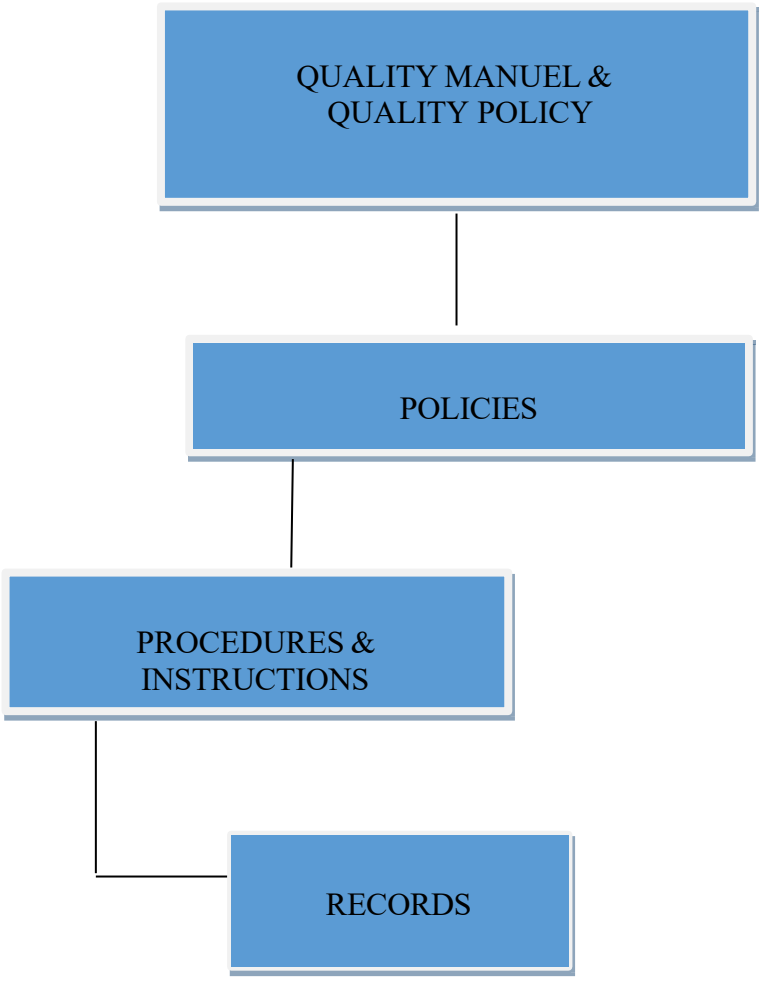
DOCUMENTATION HIERARCHY



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QUALITY POLICY

Medical Devices Technology International (MDTi) Limited (the 'Organization') is committed to provide defect free products to its customers on time and within budget.

The Organization operates a Quality Management System that operates to 13485:2016 certification, including specific to the commercialization of medical devices that is compliant to the Medical Devices Regulation (EU) 2017/745.

The management and control of all subcontractors and suppliers is undertaken by Medical Devices Technology International Ltd (MDTi)

The management is committed to:

1. Taking and maintaining a risk base approach to product MDTi places on the market
2. Ensuring the safety and performance of products meets regulatory compliance.
3. Develop and improve the Quality Management System
4. Continually improve the effectiveness of the Quality Management System
5. The enhancement of customer satisfaction
6. Establish and maintain a Medical Devices Technical file for each product

The management has a continuing commitment to:

1. Ensure that customer needs and expectations are determined and fulfilled with the aim of achieving customer satisfaction
2. Communicate throughout the Organisation the importance of meeting customer needs and all relevant statutory and regulatory requirements.
3. Establish the Quality Policy and its objectives
4. Ensure that the Management Reviews set and review the quality objectives, and reports on the Internal Audit results as a means of monitoring and measuring the processes and the effectiveness of the Quality Management System and to review and meet regulatory revisions and statutory requirements
5. Ensure the availability of resources
6. Retain obsolete documents for a period of 7 years in a controlled archive structure
7. All records will be retained within the appropriate files for at least the lifetime of the product
8. To maintaining a quality system to the requirement of ISO 13485:2016

The structure of the Quality Management System is defined in Quality Procedures Manual.

All personnel understand the requirements of this Quality Policy and abide with the contents of the Quality Procedures Manual.

The Organization complies with all relevant statutory and regulatory requirements. Promote awareness of all regulatory requirements to pertinent stakeholders, in particular, suppliers. The Organization constantly monitors its quality performance and implements improvements when appropriate.

This Quality Policy is regularly reviewed in order to ensure its continuing suitability.

Copies of the Quality Policy are made available to all members of staff. Copies of the minutes of Management Reviews, or extracts thereof, are provided to individual members of staff in accordance with their role and responsibilities as a means of communicating the effectiveness of the Quality Management System.

Signed: Mlevermore **Name:** Prof Martin Levermore **Date:** 12/12/2024

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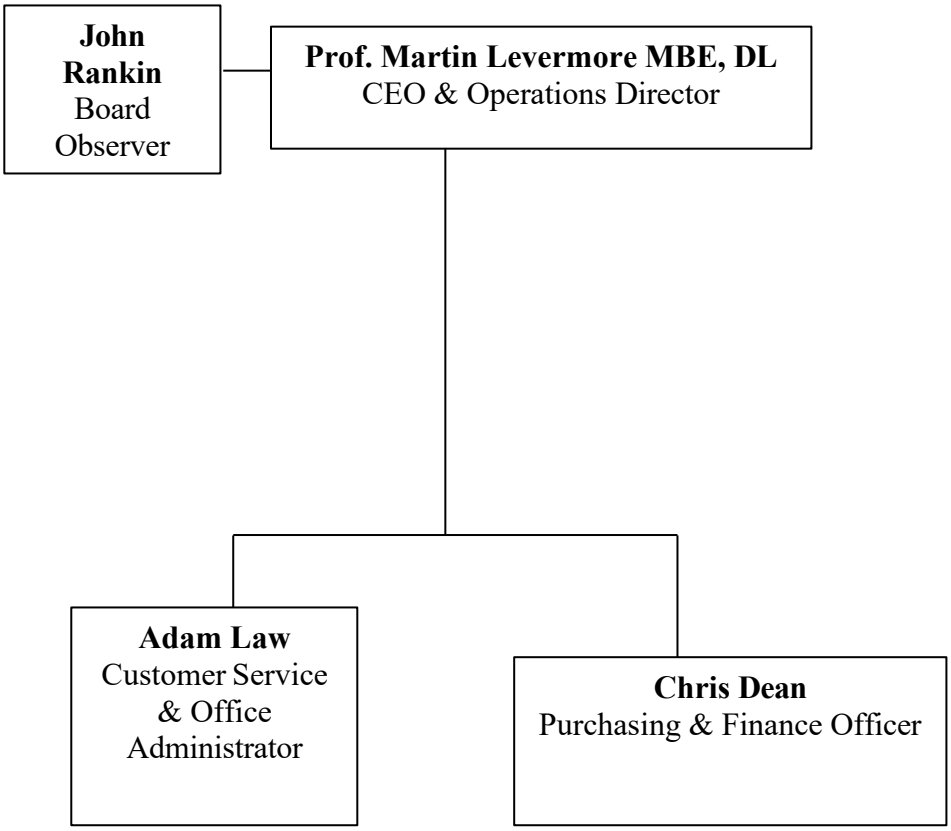
Company Structure as of April 2021



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1 - SCOPE

Control of manufacture and distribution of non-sterile devices: intravenous drips hooks, lower limb rehabilitation devices, vaginal dilator, nasal clip for nose bleeds, and rectocele devices.

To achieve this goal, the company has implemented a Quality Management System (QMS) in accordance with the Medical Devices Regulation (EU) 2017/745, and ISO/IEC 13485:2016 and in accordance with all other statutory regulations and obligations.

The QMS demonstrates the Organization's:

1. Ability to consistently provide products that are safe to meet customer and applicable regulatory requirements by the commercialization of innovative medical devices.

2. Aim to enhance customer satisfaction through the effective application of the Quality Management System, including processes for continually improvement of the System and the assurance of conformity to customer and applicable regulatory requirements.

3. To provide Service deliverables incorporating products from within the Product Portfolios.

4. Quality Management System applies to the provision of trusted and managed products and services to internal and external customers of Medical Devices Technology International Ltd (MDTi).

5. The Quality Management System (QMS) encompasses Medical Devices Technology International Ltd (MDTi) office at the Kace Building, Victoria Passage, Wolverhampton WV1 4LG, the business activities relating to the provision of purchasing/financial control, outsourcing , product realization as this pertain to physical products and any software and the management of company customers via the internal IT systems and networks for back-end business (such as office software, fax , emails, telephony, contracts, storage , website and reports).

Whenever any requirement(s) of the International Standard cannot be applied they are excluded. The rationale for all such exclusions is clearly set out.

Such exclusions do not affect the Organization's ability, or responsibility, to provide product that are safe and meet customer and applicable regulatory requirements.

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1a – Non-applications/ exclusions

Excluded Clauses	***Non-applications/exclusion***	***Justification***
7.3.1 -7.3.5	N/A	The organization does not undertake the initial design of products since this is an NHS function
7.5.2	N/A	Cleaning methods are included in user manuals supplied
7.5.3	exclusion	The organization nor any of its suppliers undertake the installation of any medical devices produced offered by the organization
7.5.4	Exclusion	The organization nor any of its suppliers provide servicing of medical devices that it produces
7.5.5	Exclusion	The organization nor any of its suppliers undertake or supply medical devices that require sterilization. Sterilization is outside the scope of the business activities.
7.5.6	N/A	This requirement is outsourced to approved key supplier and assurance provided by them that they have the capabilities to meet this requirement on behalf of the organization when undertaking manufacturing of products
7.5.7	Exclusion	The organization does undertake any sterilization activities or provide any sterile barrier systems.
7.5.9.2	Exclusion	The organization does not manufacture or supply implantable medical devices
7.6	Exclusion	The company does not manufacturer or supply any products that have a Control of monitoring and measuring function

2 - NORMATIVE REFERENCES

At the time that this Quality Procedures Manual was prepared the entire fundamentals and vocabulary relating and applied to the International Standard are set out in the document titled:

ISO 9000:2015, Quality Management Systems — Fundamentals and Vocabulary.

Parties to agreements based on this International Standard are encouraged to adopt the amendments contained in any subsequent editions of the International Standard that may be published. Members of ISO and IEC maintain registers of currently valid International Standards.

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3 - TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply in use in Quality Management Systems:

Advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:
— use of a medical device,
— modification of a medical device,
— return of the medical device to the organization, or
— destruction of a medical device

Note 1: Issuance of an advisory notice can be required to comply with applicable regulatory requirements.

Authorized representative
natural or legal person established within a country or jurisdiction who has received a written mandate from the organization to act on its behalf for specified tasks with regard to the latter's obligations
under that country or jurisdiction's legislation.

Clinical evaluation
assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the organization.

Complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.

Note 2: This definition of "complaint" differs from the definition given in ISO 9000:2015.

Distributor
natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

Note 3: More than one distributor may be involved in the supply chain.
Note 4: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

Implantable medical device
medical device which can only be removed by medical or surgical intervention, and which is intended to:
— be totally or partially introduced into the human body or a natural orifice, or
— replace an epithelial surface or the surface of the eye, and
— remain after the procedure for at least 30 days

Note 5: This definition of implantable medical device includes active implantable medical devices.

Importer
natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

Labelling
label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

Lifecycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

Manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name, whether or not such a medical device is designed and/or manufactured by that organization themselves or on their behalf by another person(s)

Note 6: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.
Note 7: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.
Note 8: "Design and/or manufacture", as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.
Note 9: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the

instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.
Note 10: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.
Note 11: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.
Note 12: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

Medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related articles, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose (s) of:
— diagnosis, prevention, monitoring, treatment or alleviation of disease.
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury.
— investigation, replacement, modification, or support of the anatomy or of a physiological process.
— supporting or sustaining life.
— control of conception.
— disinfection of medical devices.
— providing information by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 13: Products which may be considered to be medical devices in some jurisdictions but not in others include:
— disinfection substances.
— aids for persons with disabilities.
— devices incorporating animal and/or human tissues.
— devices for *in vitro* fertilization or assisted reproduction technologies.

Medical device family
group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function

Performance evaluation
assessment and analysis of data to establish or verify the ability of an *in vitro* diagnostic medical device to achieve its intended use

Post-market surveillance
systematic process to collect and analyze experience gained from medical devices that have been placed on the market

Product
result of a process

Note 14: There are four generic product categories, as follows:
— services (e.g. transport).
— software (e.g. computer program, dictionary).
— hardware (e.g. engine mechanical part).
— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product "automobile" consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).
Note 15: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:
— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired).
— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return).
— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission).
— the creation of ambience for the customer (e.g. in hotels and restaurants).
Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.
Hardware is generally tangible, and its amount is a countable characteristic.
Processed materials are generally tangible, and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.
Note 16: This definition of "product" differs from the definition given in ISO 9000:2015.

Purchased product
product provided by a party outside the organization's quality management system.
Note 17 to entry: The provision of product does not necessarily infer a commercial or financial arrangement.

Risk
combination of the probability of occurrence of harm and the severity of that harm.
Note 18: This definition of "risk" differs from the definition given in ISO 9000:2015.

Risk management
systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.

Sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

Note 19: The requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards.

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4 - QUALITY MANAGEMENT SYSTEM

4.1 Summary of *Requirements*	***General requirements***
4.1.1	The organization shall document a quality management system and maintain its effectiveness and continually improve in accordance with the requirements of the International Standards and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by the International Standards or applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE: Roles undertaken by the organization can include manufacturer, authorized representative, importer

	STATEMENT/PROCEDURE
1.	As part of the implementation of this Quality Management System the Organization has identified and documented in this Manual: 1. The processes needed for the Quality Management System 2. The sequence and interaction of these processes; see quality plan 3. The criteria and methods used to ensure the effective operation and control of these processes 4. Documented the organization's role as set out in the 'Scope' of this QMS which can be found on page 12 of this document. 5. The means to ensure the availability of the resources and the information necessary to support the operation and monitoring of these processes 6. The processes used to measure, monitor and analyze these processes and implement action necessary to achieve planned results and monitor continual improvement

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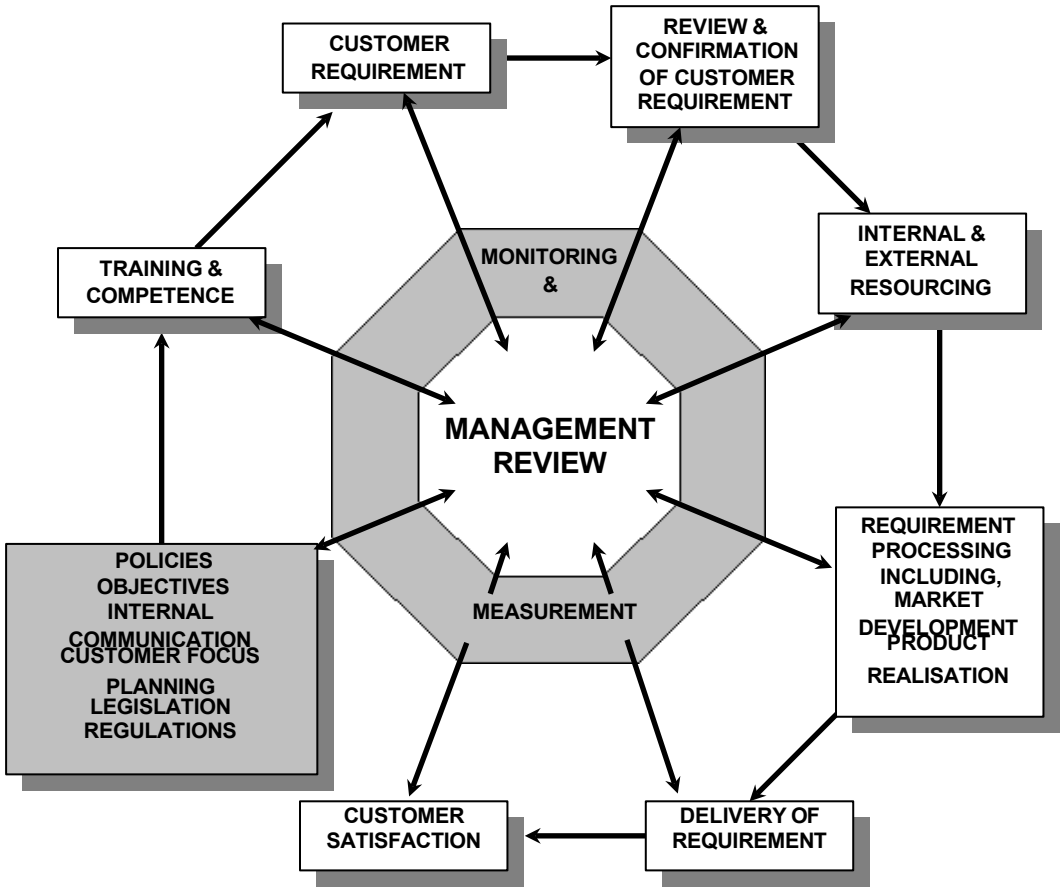
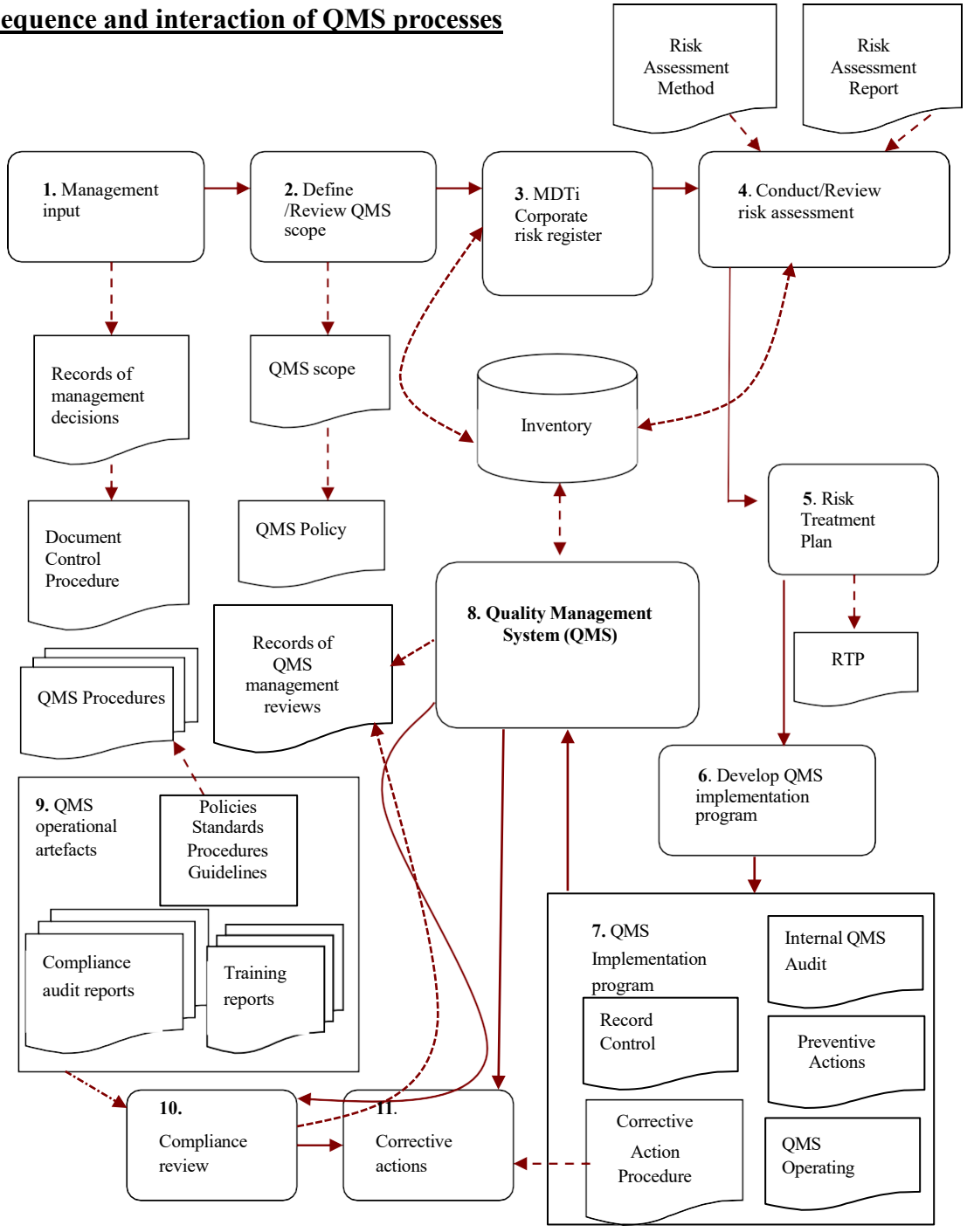
4 - QUALITY MANAGEMENT SYSTEM

4.1 Summary of *Requirements*	***General requirements***
4.1.2	The organization shall: a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization. b) apply a risk base approach to the control of the appropriate processes needed for the quality management system; c) determine the sequence and interaction of these processes.

	STATEMENT/PROCEDURE
1.	The Quality Management System of MDTi is based on the following process model:
2.	As part of the management of the QMS process the Organization shall apply a risk base



	approach method as outlined in its document, Risk management guide Issue 4.1.2' (Appendix 4) and, when required, makes changes to the Quality Management System in order to ensure that it continues to meet management requirements and market conditions.
3.	**Sequence and interaction of QMS processes** 

4.1 Summary of *Requirements*	**General requirements**
4.1.3	For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective. b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes. c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes. d) monitor, measure as appropriate, and analyze these processes. e) establish and maintain records needed to demonstrate conformance to the International Standard and compliance with applicable regulatory requirements.

	STATEMENT/PROCEDURE
1.	The Organization has determined the criteria and method needed to ensure that both operation and control of processes are effective through the routine adhesion to the following: a) Planned internal audits reports produced in-line with 'Audit Calendar' schedule. Information presented via document MDTi Ref00008.2.2QM (Audit report Template v1.5). b) Any areas of non-conformity rise on document NCPAR No. Version 1.4 and process followed according to document 'Compiling and filling Non-conformance forms' that is held on internal server. c) All information required to support the operation and monitoring of the QMS processes are held on the company's international server within QMS flow chart folder and flow charts should be followed to ensure consistency. d) Implementation of actions necessary to achieve planned results and maintained effectiveness of the processes shall be recorded via: • Minutes of team meetings • Audit reports • CPA reports • PMS reports e) Monitoring and measuring/analyze of processes will be undertaken once a year at an annually at management review. f) Records needed to demonstrate conformance to the International Standards and applicable regulatory requirements: • The scope of the quality management system (clause 4.3). • Documented information necessary to support the operation of processes (clause 4.4) • The quality policy (clause 5.) • The quality objectives (clause 6.2) • Copies of the International Standards subject to the requirements of clause 7.5
4.1 Summary of *Requirements*	**General requirements**
4.1.4	The organization shall manage the quality management system processes in accordance with the requirements of the current International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system. b) evaluated for their impact on the medical devices produced under this quality management system. c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.

	STATEMENT/PROCEDURE
1.	The Organization shall undertake a full review of its QMS in line with most update International Standards and applicable regulatory requirements. Evaluation of any impact shall be reported in version change to this manual and recorded at the 'Revision and Amendment Register' page of this manual.
2.	In addition to (1) above, evaluation should be made in the following documents: • Scope • Quality Policy • Quality Objectives
3.	A complete evaluation of all medical devices produced by the organization shall be reviewed and determine the impact under the current QMS. All revisions to medical devices should be recorded in each Medical Device files.
4.	All processes and documents are controlled in accordance with the requirements of the International Standards and applicable regulatory requirements.

4.1 Summary of *Requirements*	**General requirements**
4.1.5	When the organization outsources any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.

	STATEMENT/PROCEDURE
1.	The Organization outsources manufacturing of products. Selection of manufacturer is determined not purely on the proximity to the company but by the following formal criteria: • Quality • Availability of technical personnel • Historical supplier Performance • Evaluation of Previous work undertaken in similar field • Customers' Requirements • Willingness to amortize • Good Communication and regular updates/technical information supplied as and when requested • Compliance with ETI base code Each of the above criteria is given a score from 1 to 5, with 5 being the highest score attainable for a section. Contract manufacturers must demonstrate their ability to achieve a minimum aggregate score of 30 marks to be accepted onto and be maintained on the approved suppliers' list of the company. The Approved Suppliers' list is held on the Company's server and should be reviewed at least every three (36) months or as more frequently as it is deemed appropriate to ensure suppliers on the list remain compliant with the organization's requirement in order that it maintains compliance to the international standards, customers' requirements and applicable regulation.
2.	In addition to (1) above, no subcontractor shall be entered on the list of 'Approved Suppliers' until there is in place a written quality agreement between them and MDTi.

4.1 Summary of *Requirements*	**General requirements**
4.1.6	The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).

	STATEMENT/PROCEDURE
1.	In-line with EU, EudraLex Volume 4. Annex 11 (Appendix 5) all software used in the day-to-day management of the organization, and their effectiveness shall be governed and controlled by the following company's documentary procedures and policies to ensure software validation and revalidation is compliant, procedures that shall be followed are summarized in the following company's documents: a. Statement of applicability b. Risk treatment plan c. Malicious Software Policy – Doc. Ref: ISM/MSP- 01 d. Matrices for Asset Valuation and Risk Analysis – Doc. Ref: ISM/GL/04 e. Incident Reporting procedure – Doc. Ref: ISM/IR/01 f. System Backup - Doc. Ref: ISMSYS Back/01 g. Preventive Action Procedure – Doc. ROR-PA h. Measurement of Controls - Doc. F-MCE-01
2.	A list of all software assets used in the organization is held under an excel document 'MDTi 27k Asset Register' version 1.15 15/07/2021

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4 - QUALITY MANAGEMENT SYSTEM

4.2	**Documentation requirements**
4.2 1	**General**
Summary of Requirements	The International Standard recognises that the extent of the requirements for documented procedures differs according to the characteristics of the individual organization. However, as a minimum, in order to satisfy the requirements of the International Standard a formal written Quality Policy, Quality Objectives and a Quality Procedures Manual are generally considered essential. A technical file and a project file shall be kept for every product and any other documentation specified by national or regional regulations

	STATEMENT/PROCEDURE
1.	The following documents together define the Organization's Quality Management System and ensure the effective operation and control of its procedures: 1. The Quality Policy 2. The Quality Objectives 3. This Quality Procedures Manual 4. Medical Device files (i.e. technical folders) 5. Project Folders 6. Customer specifications 7. Office Protocols and Guidelines 8. Health and Safety Policy, Statements and Risk Assessments 9. British Standards and Legislation. The QMS, through its medical device files should promote the awareness of regulatory requirements and which should be regularly reviewed for any revisions periodically. All subcontractor control documentation or technical documentation should be held within the medical device file.

QUALITY PROCEDURES MANUAL

4 - QUALITY MANAGEMENT SYSTEM

4.2	**Documentation requirements (Continued)**
4.2.2	**Quality Procedures Manual**
Summary of Requirements	The Quality Procedures Manual contains a description of all of the components and requirements of the Quality Management System. It also identifies and justifies all exclusions from the requirements of the International Standard. It must also provide a description of how, within the Organization's activities, the sequence and interaction of processes takes place.

	STATEMENT/PROCEDURE
1.	Management ensures that this Quality Procedures Manual includes: 1. The defined scope of the Quality Management System 2. Documented procedures or reference to them within other documents 3. Any exclusions identified and justified 4. A description of the interaction of processes The quality manual shall outline the structure of the documentation used in the QMS.
2.	Effective implementation of the Quality Management System is monitored on an informal basis, as part of the Organization's day-to-day operations.
3.	The Quality Manager deals with instances when the Quality Management System is not correctly implemented.
4.	Breaches of the Quality Management System are investigated; corrective and preventative action are implemented
5.	Such breaches are taken into account when reviewing: 1. The overall operation of the Organization's Quality Management System 2. The Quality Procedures Manual, to ensure that it is up to date and accurately reflects the working practices of the Organization 3. Staff training requirements

QUALITY PROCEDURES MANUAL

4 - QUALITY MANAGEMENT SYSTEM

4.2	**Documentation requirements (Continued)**
4.2.3	***Medical Device File***
Summary of Requirements	For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements. The content of the file(s) shall include, but is not limited to: a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use. b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question c) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII. d) specifications for product. e) specifications or procedures for manufacturing, packaging, storage, handling and distribution. f) procedures for measuring and monitoring. g) as appropriate, requirements for installation. h) as appropriate, procedures for servicing. i) the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

	STATEMENT/PROCEDURE
1.	In accordance to Annex II 'Technical Documentation' of MDR (EU) 2017/745 for each medical device there shall be establish a separate identifiable file. Each file shall be suitably indexed across six (6) sections as follows: 1. Device Description and Specification, including variants and accessories 2. Information to be supplied by the Manufacturer. 3. Design & manufacturing information. 4. General Safety & performance requirements. 5. Benefit-risk analysis & risk management (product life cycle ref to doc. ISO 14971:2019 – Application of risk Management to medical devices). 6. Product verification & validation

4.2	**Documentation requirements (Continued)**
4.2.4	***Control of documents***

Summary of Requirements	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements. There must be documented procedures that must define controls needed to: A documented procedure shall define the controls needed to: a) review and approve documents for adequacy prior to issue. b) review, update as necessary and re-approve documents. c) ensure that the current revision status of and changes to documents are identified. d) ensure that relevant versions of applicable documents are available at points of use. e) ensure that documents remain legible and readily identifiable. f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled. g) prevent deterioration or loss of documents. h) prevent the unintended use of obsolete documents and apply suitable identification to them. The organization shall ensure that changes to documents are reviewed and approved by designated function. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record, or as specified by applicable regulatory requirements.

	STATEMENT/PROCEDURE
	Quality Procedures Manual:
1.	The CEO has approved this Quality Procedures Manual and will approve all subsequent issues.
2.	A controlled copy of the Quality Procedures Manual is held on the Organization's computer system and is maintained by the Quality Manager.
3.	A further controlled hard copy is retained for reference. Other issues of the Quality Procedures Manual will be issued as either controlled or uncontrolled documents.
4.	Proposed changes to the Quality Procedures Manual are identified during the day-to-day activities as well as more formally during the Management Review process described in Section 5.6.
5.	Proposed changes are reviewed and, if appropriate, adopted by the Quality Management Team after considering all of the relevant information.
6.	When adopted, changes are made to the controlled copy of the Quality Procedures

	Manual and the appropriate personnel are notified of the change.
7.	All records are issued and controlled from the Office. All records must be retained for at least the lifetime of the product
8.	All document templates used within the Organization are specifically printed or else templates kept in the computer system. Where they are not generated by the system, they are maintained as controlled issue copies in a folder appendix to this Quality Procedures Manual.
9.	Externally produced documents, i.e. suppliers, customers or any specifications or conditions etc. are a controlled issue from the issuing authority whenever considered necessary.
10.	A technical library of reference books, standards, trade literature and other relevant documents is maintained.
11.	As updates are received, they are filed in the library and the previous item removed.
12.	If the previous item is required for reference it is marked across the front cover in red letters **"MDTi Ref. Only"**.
13.	All customers' and employees' personnel details that are held on computer or as hard copies are subject to the General Data Protection Regulations (GDPR) that became enforced in the UK as of 25 May 2018.
14.	Documents and data that are to be destroyed and are of a sensitive nature are either shredded or disposed of by a recognized secure disposal method.
15.	Documents and data that are to be destroyed and are of a sensitive nature are either shredded or disposed of by a recognized secure disposal method.
16.	All commercially sensitive information, knowledge or documents with which the Organisation or any of its representatives becomes acquainted always remains confidential, and will not, under any circumstances, be passed to third parties
17.	All computers data held is treated in accordance with the requirements of the Data Protection Act 1998 amended by General Data Protection Regulations (GDPR).
18.	The Organization's computer system is backed up (currently every week) with a secure copy being stored.
19.	The integrity of the computer system and the data held on it is maintained by running background virus protection software and the maintenance of effective and regularly updated Firewalls.
20.	Below the documents and records used in the organization are detailed
21.	All records that are not in current use should be archived to central electronic folder with an index of when the record or document was moved to archived space. Archived record's folder should be inspected once a year to see if information is complaint to document retention as per table on page 36 of the QMS. All manual obsolete records will be destroyed after the effected period of retention by the use of registered documentation destruction company, company will obtain a receipt from such company that destruction of documents have been carried out lawfully and to prevailing waste directive.
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4 - QUALITY MANAGEMENT SYSTEM

Documents used within MDTi requirements

*** Or to customer specific**

Document	Preparation/ Updating	Checking/ approval	Archiving			Location of current copies
			Responsible	Location	Years *	
Quality Manual	ML	ML	ML	Office	7	Office
Medical Device Files (technical files)	ML	ML	CD	Office	7	Office
H&S Policy	ML	ML	ML	Office	7	Office
Risk Assessments	AL	ML	AL	Office	7	Office
Staff Training Forms	ML	ML	ML	Office	7	Office
Sales and Product Training forms	AL	ML	ML	Office	7	Office
Licence Agreements	ML	ML	CD	Office	7	Office
Manuf/Quality Agreements	CD	ML	CD	Office	7	Office

QUALITY PROCEDURES MANUAL

4 - QUALITY MANAGEMENT SYSTEM

4.2	**Documentation requirements (Continued)**
4.2.5	***Control of records***
Summary of Requirements	A schedule of records addressed within the Quality Management System must be prepared and maintained. The schedule must include minimum periods of retention and establish standards for their identification, storage and disposition. The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

	STATEMENT/PROCEDURE
1.	The Management Representative/Quality Manager is responsible for keeping the following records for a minimum period of 7 years or as required by statutory, regulatory and/or contractual requirements, whichever is the longer, in order to demonstrate conformity to the requirements and effective operation of the Quality Management System: 1. Previous Management Review Records 2. Quality Audit Reports 3. Management Information records 4. Staff training records 5. Non-conformance records including customer complaints 6. Customer satisfaction records 7. Completed project files 8. Computer back up data 9. Delivery performance tracking
2.	This procedure is applicable to all records that are generated and listed in this procedures manual and those that affect any aspect of quality.
3.	All records are maintained in a safe and secure environment, and in a way that facilitates their ready retrieval.
4.	The Quality Manager is responsible for: 1. Identifying and specifying the records that are subject to control

	2. Nominating individuals responsible and accountable for every record 3. Specifying the contents of records (through procedures) 4. Recording disposal

4 - QUALITY MANAGEMENT SYSTEM

	STATEMENT/PROCEDURE (Continued)
4.2.5	***Control of records***
5.	The storage system ensures that records are adequately protected, remain legible and are readily identifiable.
6.	Records are stored and maintained in a manner to make them readily retrievable, in facilities that provide an environment to minimise deterioration or damage and prevent loss
7.	The Management Representative/Quality Manager maintains a Record Control Schedule with document specific requirements (as appropriate) for the identification, collating, indexing, filing, storage and maintenance of records.
8.	Quality records are reviewed annually by the Management Representative/Quality Manager and those retained more than the specified retention period are disposed of or for at least the lifetime of the product.
9.	If contractually agreed longer periods of retention apply the relevant files and/or documents are marked accordingly.
10.	Details of the records maintained by the organization are listed in the table below
11.	Should the Company receive confidential health information personnel must follow the company's MDTi's Confidentiality and Data Protection Assurance policy Doc. Requirement 10-202 and 10-211. Further guidance on Company's GDPR in this matter should be directed by MDTi Information Governance Policy Doc. Requirement 10- 115.
12.	When a document has been revised, systems must be operated to prevent inadvertent use of superseded documents. It is especially important that only current documentation should be available for use [Good Documentation Practice - GDP]. A further important consideration is to ensure that the records can be kept in an orderly fashion to facilitate retrieval at some unspecified time in the future. To help with efficient location of records, attention should be paid to numbering including the version number and date for traceability.

Records held with MDTi

Record	Preparation/ distribution	Archiving			Distribution List
		Responsible	Location	Years*	
Loan Samples Out and Returns	AL/CD	AL	Office	5	None
Customer Feedback Forms	AL/CD	AL	Office	5	Yes
Complaints	AL	AL	Office	5	Yes
FDA certification Files	ML	CD	Office	3	Yes
PPA Files	ML	CD	Office	5	None
Staff Training Records	ML	ML	Office	7	None
Staff Records	ML	ML	Office	7	None
Board Minutes	ML	ML	Office	7	Yes
Medical Device files	ML	ML	Office	7	None

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.1	***Management commitment***
Summary of Requirements	Senior management must: a) Establish quality policy, b) Ensure quality objectives are established, c) Ensure availability of resources d) Maintain its effectiveness Clear evidence of the management's commitment to the Quality Management System, including its development and improvement, must be made available. The ability to demonstrate that the importance of meeting all relevant statutory and regulatory requirements coupled with those of the Organization's customers has been communicated throughout the Organization, together with the provision of evidence of regular Management Reviews shall satisfy this requirement.

	STATEMENT/PROCEDURE
1.	The Organization's Quality Policy includes a commitment from management to develop and continually improve the Quality Management System by: 1. Communicating throughout the Organization the importance of meeting customers' requirements 2. Communicating throughout the Organization the importance of meeting all relevant statutory and regulatory requirements 3. Establishing the Quality Policy and its objectives 4. Conducting Management Reviews 5. Ensuring the availability of resources
2.	The Organization's quality objectives and goals are reviewed to determine whether they remain relevant to customer requirements. The reviews take place as considered necessary in accordance with the Management Review procedures set out in Section 5.6 and consider matters raised at previous meetings.
3.	Document signature authorization is listed in the table below:

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Signature Authorisation

Document/Process E.g…….	**CEO**	Operations Director	Clinical	Procurement Officer	Admin & Mktg
Licencing agreement	Yes				
Memo	Yes		Yes	Yes	Yes
Visit Report	Yes		Yes	Yes	Yes
Minutes of Meetings	Yes		Yes	Yes	Yes
Audit Reports	Yes		Yes		
Fax	Yes	Yes	Yes	Yes	Yes
Recruitment	Yes		Yes		
Personnel Timesheets	Yes		Yes		
Input to Medical Library	Yes		Yes	Yes	Yes
Marketing Literature	Yes		Yes		
Internal Training	Yes		Yes		
Clinical Training			Yes		
Quality Release of Products	Yes		Yes		Yes

5 - MANAGEMENT RESPONSIBILITY

5.2	***Customer Focus***
Summary of Requirements	Top management shall ensure that customer requirements and applicable regulatory requirements are determined and are met. (see 7.2.1 and 8.2.1)

	STATEMENT/PROCEDURE
1.	Customer focus is ensured by the implementation of the contract review processes set out in Section 7.2, (Customer-related processes) and of the activities of the customer service function
2.	Feedback from customer monitoring is actively undertaken. How this is reviewed is detailed in Section 8.2.1 is reviewed during Management Review.

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.3	***Quality Policy***
Summary of Requirements	The Quality Policy must: a) Be appropriate to the organization. b) Include a commitment to comply with the Quality Management System and to satisfy applicable requirements. c) Include a commitment to maintain the effectiveness of the Quality Management System. d) Provide a framework for establishing and reviewing quality objectives. e) Be communicated and understood within the Organization. f) Be reviewed for continuing suitability and continual improvement of the QMS.

	STATEMENT/PROCEDURE
1.	In order to provide evidence of the Organization's commitment to the Quality Policy, the Policy is regularly reviewed, and any changes approved as part of the formal Management Review proceedings. These reviews and all approved changes are recorded in the minutes of the Management Reviews.
2.	Copies of the Quality Policy are made available to all members of staff. Copies of the minutes of Management Reviews, or extracts thereof, are provided to individual members of staff in accordance with their role and responsibilities as a means of communicating the effectiveness of the Quality Management System.
3.	As a component of the Quality Management System a copy of the Quality Policy may be issued to quality related suppliers and to customers whenever considered necessary.

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.4	***Planning***
5.4.1	***Quality objectives***
Summary of Requirements	Quality objectives must be established that are measurable and meet applicable regulatory requirements, in accord with the Quality Policy and include a commitment to continual improvement. These objectives must also address product requirements and be established at relevant functions and levels in the organization.

	STATEMENT/PROCEDURE
1.	Quality objectives are established as part of the day-to-day management and are more fully defined by the application of the procedures set out in Section 7.1, (Planning of product realization).
2.	The Organization considers that implementing the contents of this Quality Procedures Manual to meet BS EN ISO 13485:2016 requirements constitute the primary quality objective.
3.	The organisation understands that a first-class service is vital to retaining the long-term patronage of customers.
4.	Our commitment is to provide all customers with the best possible service.
5.	The ability to supply all contract requirements to customers' stated needs and delivered both on time and to budget is an intrinsic element of the trading base of the Organization.

5 - MANAGEMENT RESPONSIBILITY

5.4	*Planning (Continued)*
5.4.2	***Quality Management System planning***
Summary of Requirements	Senior management must ensure that the planning of the QMS is carried out in order to meet the requirements of 4.1 and 4.2 as well as quality objectives. Determine the risks and opportunities that need to be addressed. Any changes to the Quality Management System, however brought about, do not detract from its integrity.

	STATEMENT/PROCEDURE
1.	Quality Management System planning forms part of the Management Review process described in Section 5.6.
2.	The day-to-day objectives of the Organization are determined and amended in order to reflect the specific nature of individual work and contracts in the light of the decisions taken at Management Review.
3.	Specific work planning is more fully detailed in Section 7.1 of this Quality Procedures Manual.

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.5	***Responsibility, authority and communication***
5.5.1	***Responsibility and authority***
Summary of Requirements	Senior management must ensure that responsibilities and authorities are properly defined and documented and effectively communicated throughout the Organization. Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

	STATEMENT/PROCEDURE
1.	Responsibilities and authorities, together with the identity of those responsible for communicating them throughout the Organization, are illustrated in the organogram in the introduction to this Manual.
2.	Job descriptions are held centrally.
3.	Cross functional teams meet according to the meetings plan below

Meetings held within MDTi

Meeting	Invitation by	Frequency approx.	Participants	Participants from other Companies	Minutes yes/no
Monthly Team Meetings	ML	Monthly	ML, AL, CD,	No	Yes
Quality Management Review Meeting	ML	Yearly	ML, AL, CD	No	Yes
Sales Meetings	ML	Monthly	AL/CD	No	No
Board Meetings	ML	Quarterly	JR, ML, Investors	No	Yes
Medical Advisory Brd mtgs	ML	When required	ML, AL, CD, Adv Brd	No	Yes
Review meeting with NHS	ML	When required	ML, NHS	Yes	Yes
Annual Meeting and Auditing of Product	ML	Quarterly	ML, CD, Manufr.	Possible	Yes
Shareholders meetings	ML	When required	Board + Investors	Possible	Yes

5 - MANAGEMENT RESPONSIBILITY

5.5	*Responsibility, authority and communication (Continued)*
5.5.2	***Management representative***
Summary of Requirements	A member of management must be appointed as the Management Representative /Quality Manager (QM). Except in large organisations this is not necessarily a fulltime role. On a day to day basis the QM is responsible for the Quality Management System. The QM must ensure that effective Quality Management System processes are implemented and maintained. Another of the QM's responsibilities is to regularly report on the progress and improvement (8.5) of the Quality Management System to senior management, in particular at Management Reviews. The QM promotes awareness of regulatory and customer requirements and monitors and analyses the feedback from customers.

	STATEMENT/PROCEDURE
1.	The CEO is responsible for promoting customer awareness by implementing and ultimately overseeing all aspects of the Quality Management System.

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.5	*Responsibility, authority and communication (Continued)*
5.5.3	***Internal communication***
Summary of Requirements	Top management must ensure effective internal and external communications must be established and maintained in order to ensure that all those who are in any way responsible for processes relating to the Quality Management System are aware of those quality processes that have been approved by the Organisation's management.

	STATEMENT/PROCEDURE
1.	The effectiveness of the Quality Management System is communicated throughout the Organization by providing copies of the minutes of Management Reviews, or extracts thereof, to individual members of staff in accordance with their role and responsibilities.
2.	Appropriate methods for internal and external communication are used according to nature and require distribution of the information.

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.6	***Management Review***
5.6.1	***General***
Summary of Requirements	The Standard places a prime requirement on senior management to review all aspects of its Quality Management System at regular, pre-determined intervals. In particular these reviews must address the on-going effectiveness, adequacy and suitability of the Quality Management System. The review shall include assessing opportunities for improvement and need for changes to the QMS, including quality policy and objectives. All such Management Reviews must be recorded and maintained, and the records kept in accordance with the procedures set out in this Manual. (See 4.2.5).

	STATEMENT/PROCEDURE
1.	As part of the initial implementation of the Quality Management System, a Management Review is held at least a month prior to registration in accordance with the procedures set out in this section.
2.	A Management Review is carried out at not greater than 12 monthly intervals and addresses, in addition to general matters, the following: 1. Review of non-conformance records 2. Status of preventive and corrective actions 3. Follow up actions from earlier Management Reviews 4. Changes in the Organization's operational environment that could affect the Quality Management System, including requirements for additional or revised resources 5. The Organization's Quality Policy, objectives and goals to determine whether they remain relevant to the requirements of customers and management 6. The overall operation of the Organization's Quality Management System to determine its continuing suitability and effectiveness 7. The performance of suppliers and sub-contractors, including any required actions resulting from unsatisfactory performance (Appendix 2). All new suppliers must complete the Suppliers Evaluation Questionnaire (Appendix 3) 8. Staff training, re-training and competence requirements 9. Customer satisfaction levels and plans for continual improvement

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.6	*Management Review (Continued)*
5.6.2	***Review input***
Summary of Requirements	The Management Review must consider: a) Feedback b) Complaint handling c) Reporting to regulatory authorities d) Audits e) Monitoring and measurement of processes f) Monitoring and measurement of product g) Corrective action h) Preventive action Status of preventive and corrective actions i) Follow-up actions from previous Management Reviews j) Changes that could affect the Quality Management System k) Effectiveness of actions taken to address risks and opportunities l) Adequacy of resources m) Recommendations for improvement n) New or revised regulatory requirements o) Resource needs

	STATEMENT/PROCEDURE
1.	Records made available to facilitate the Management Review include, but are not limited to: 1. Previous Management Review Records 2. Quality Audit Reports 3. Management Information records 4. Staff suggestions 5. Staff training and competency records 6. Non-conformance records including those incurred by suppliers and customer complaints 7. Corporate risk register 8. Asset register 9. Regulatory register 10. Customer satisfaction records
2.	The Management Representative/Quality Manager reviews and summarizes quality record trends and highlights areas of concern and possible opportunities to be addressed during Management Reviews.

QUALITY PROCEDURES MANUAL

5 - MANAGEMENT RESPONSIBILITY

5.6	*Management Review (Continued)*
5.6.3	***Review output***
Summary of Requirements	The Management Review output must address: a) Improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes b) Improvement of product related to customer requirements c) Changes needed to respond to applicable new or revised regulatory requirements d) Resource needs

	STATEMENT/PROCEDURE
1.	The findings of every Management Review are recorded and kept in accordance with the procedures set out in Section 4.2.5 and include details of: 1. Actions agreed to improve the Quality Management System and its processes 2. Actions agreed to improve the service that the Organization provides to its customers 3. Actions agreed to meet revised resource requirements and regulatory requirements 4. Improvement of product related to customer requirements 5. Corrective and preventive actions taken and planned 6. Opportunities for improvement 7. Targets and responsibilities for implementing any agreed action

QUALITY PROCEDURES MANUAL

6 - RESOURCE MANAGEMENT

6	*Resource Management*
6.1	***Provision of resources***
Summary of Requirements	The Organisation shall determine and provide that adequate resources are provided: a) To implement the QMS and to maintain its effectiveness b) To meet regulatory and customer requirements

	STATEMENT/PROCEDURE
1.	The identification of revised or additional resources required to implement and improve the processes of the Quality Management System takes place as part of day-to-day management, including procedures noted in Section 6.2 and 8.2.1, as well as part of the Management Review procedures described in Section 5.6.
2.	In addition to Management Reviews, regular informal meetings take place. Significant issues are discussed, and appropriate action is agreed and implemented, as necessary.

QUALITY PROCEDURES MANUAL

6 - RESOURCE MANAGEMENT

6.2	***Human resources***
Summary of Requirements	Senior management shall ensure that all personnel whose work has a direct or indirect effect on any aspect on product quality shall be competent based on appropriate education, experience, training and skills. The organisation shall document the process(s) for establishing competence, providing needed training and ensuring awareness of personal. The organisation shall: a) Determine the necessary competence for personnel performing work affecting product quality b) Provide training or take other actions to achieve or maintain the necessary competence c) Evaluate the effectiveness of the actions taken d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives e) Maintain appropriate records of education, training, skills and experience Note: the methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.

	STATEMENT/PROCEDURE
1.	All new members of staff receive appropriate induction training during their probationary period. This includes product training, an introduction to the Quality Policy and their individual role in the operation of the Quality Management System.
2.	Staff training and competence are assessed considering everyone's education, skills and experience.
3.	Requirements for further training are identified as part of day-to-day management and as part of the Management Review process set out in Section 5.6.
4.	Training can take place either internally under the guidance of an already trained employee, or externally when specialist training is required.
5.	A record of staff training and competence is kept including such details as: 1. Level of competence attained 2. Date and duration of the training or event 3. Training and/or activities undertaken 4. *Qualifications and/or certificates attained* 5. *Ongoing and/or future training and/or re-certification requirements*

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6.3	***Infrastructure***
Summary of Requirements	Senior management is responsible for identifying, providing and maintaining an adequate infrastructure to achieve conformity to product requirements. The components of the infrastructure may include buildings, workspace and associated utilities, process equipment (both hardware and software), transport equipment and communication systems. The organization shall document requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Records of maintenance should be maintained (4.2.5)

	STATEMENT/PROCEDURE
1.	No product is manufactured on company's site; all production is outsourced.
2.	Products received on site are to be batched checked, a sample batch is inspected, and outcome recorded prior to storage or return for rework to manufacturer.
3.	Batches of products must be clearly identified and separated from each of when being stored.
4.	Quality related computer files are maintained in accordance with the relevant procedures set out in Section 4.2.5 (Control of documents).
5.	The Organization's computer system is serviced and maintained by experienced personnel.
6.	***All portable electrical equipment is PAT tested annually in accordance with the current regulations***
7.	***All computers are virus protected. No software may be loaded onto any of the Organization's computers without prior approval and it being fully virus checked.***
8.	***For the purposes of this Quality Management System, all other elements of the infrastructure are treated as resources and provided, maintained, checked and replaced accordingly. This is administered by the application of the relevant procedures set out in Sections 7.5.1 (Control of production and service provision) and 7.6 (Control of monitoring and measuring equipment).***

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6.4 **Summary of** ***Requirements***	***Work environment and contamination control***
6.4.1	***Work environment***
Summary of Requirements	The Organisation shall identify, determine and manage all aspects of the work environment needed to achieve conformity to product requirements. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance; b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

	STATEMENT/PROCEDURE
1.	Senior management ensures that a suitable environment is maintained that provides safe systems of work and the ability to achieve conformity to product and/or service requirements.
2.	Staff facilities and the workplace are maintained in an acceptable condition to ensure that all staff can carry out their duties effectively and efficiently.
3.	First aid kits and fire extinguishers are provided and maintained throughout the Organization.
4.	Pest Control will be monitored as per section 6.4.2.3

6.4.2	***Contamination control***
Summary of Requirements	As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

	STATEMENT/PROCEDURE
1.	Any product received from sub-contractor that is found to be contaminated shall be immediately removed from the batch of the remaining product and placed inside a contamination box. The item shall be accompanied by a clear note of the contamination found along with suitable pictures taken of the contamination. Within 24 hours the Organization shall informed sub-contract of its findings and issue a non- conformance onto the contractor with recommended corrective action and timing for action to be carried out.
2.	No sterile products are produced by the organization as such 'Sterile' requirements are not applicable.
3.	A 3rd party pest control organization will monitor for relevant pests by regular inspections and supply a Pest Control Report which will be kept in the Site Report Folder.

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7.1	***Planning of product realisation***
Summary of Requirements	Planning of product realisation is needed to ensure: 1. Efficient delivery of the goods and services offered 2. Effective communication with customers 3. Proper management of any design or development processes The Organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the Quality Management System. Refer to Section 4.1 of this Quality Procedures Manual. In planning product realisation, the Organisation shall determine the following, as appropriate: a) Quality objectives and requirements for the product b) The need to establish processes, documents, and provide resources specific to the product c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance d) Records needed to provide evidence that the realisation processes and resulting product meet requirements (see 4.2.5) The output of this planning shall be in a form suited to the Organisation's method of operations. NOTE 1 A document specifying the processes of the Quality Management System (including the product realisation processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. NOTE 2 The Organisation may also apply the requirements given in 7.3 to the development of product realisation processes. *The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5).*

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	STATEMENT/PROCEDURE
1.	The work planning process involves determining and considering the Quality Policy, objectives and the requirements of the product and/or service requirements. This is achieved by the application of the documented Quality Management System and related processes and includes the provision of any necessary resources and validation and verification methods. *An authorized quality plan describes the interaction of processes within the organization.*
2.	Each member of staff is responsible for planning their own work.
3.	Work planning process involves determining and considering the quality objectives and the requirements of the project.
4.	Product Risk management will be conducted in accordance with ISO14971:2019 – applications of risk to medical devices (focused on product safety risks). For each product the company shall identify hazards associated with the medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of risks associated with the medical device throughout its life cycle.
5.	The Company shall document for each product : **benefit -** positive impact or desirable outcome of the use of the medical device on the health of an individual, **reasonably foreseeable misuse -** use of a product in a way not intended by the Company, but which can result from readily predictable human behaviour and **state of the art -** developed stage of technical capability at a given time as regards product relevant consolidated findings of science, technology and experience (i.e. Clinical evaluation). Risk shall be recorded in individual product risk reports and MDTi Corporate risk register. Some red flags are general in nature because they have several possible explanations. General red flags direct the Company to recognize a serious issue even though the exact issue is not life threatening or would have a detrimental impact on the human anatomy. Increasing material prices is one such general red flag that may prevent continued delivery of a product. Should a risk be rated 'Red' a full diagnostic of the issue should be undertaken and where appropriate suitable mitigation actions be put in place and monitored to reduce risk.
6.	The risk treatment mitigations that company will adopt are Treat, Transfer or Terminate. The Company will in all circumstance will seek to Treat the reason for the risk. where Treatment is not possible it will look to Transfer risk to a third-party, i.e. through insurance. If both Treating or Transferring is not possible then Company shall terminate activities surrounding the risks.

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7.2	***Customer related processes***
7.2.1	***Determination of requirements related to the product***
Summary of Requirements	During the continuance of its processing the Organisation shall determine all of the product requirements, whether or not specified by the customer. Such requirements may include any statutory and/or regulatory requirements and may include delivery and post-delivery stipulations. Along with any user training needed to ensure specified performance and safe use of the medical device.
7.2.2	***Review of requirements related to the product***
Summary of Requirements	The organisation shall review the requirements related to the product, prior to commitment to supply a product to the customer, e.g. submit tender, accept order or contract or changes to orders and shall ensure that: a. product requirements are defined and documented, b. contract or order requirements differing from those previously expressed are resolved, c. the organisation, has the ability to meet the defined requirements d. applicable regulatory requirements are met; e. any user training identified in accordance with 7.2.1 is available or planned to be available; f. the organization has the ability to meet the defined requirements. If unclear of requirements, confirmation must be made before accepting and all relevant staff must be made aware if anyone's product requirements are changed Records of the initial and any on-going reviews must be recorded. Refer to Section 4.2.5 of this Quality Procedures Manual.
7.2.3	***Customer communication***
Summary of Requirements	The organisation shall plan and document arrangements for communicating with customers in relation to: a) Product information b) Enquiries, contracts or order handling, including amendments c) Customer feedback, including complaints d) Advisory notices The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

	STATEMENT/PROCEDURE
	Communication with customers
	The organization shall provide all details relevant to its products via its website (www.mdti.co.uk) as well via other online marketplaces such as Amazon and eBay, this information can also be made available hard copy upon request.
	Communication on customers' orders
1.	Enquiries can be received verbally, by e-mail or post or via third party marketplace. The details are recorded on Sage database where this relates to Amazon orders. This will record but not be limited to: 1. Customer details 2. Contact details 3. Date 4. Action to be taken 5. Follow-up action 6. Product requirement 7. Delivery requirements
2.	On receipt of the order, a contact review process is undertaken to ensure that the product is recognized and can be supplied within the time scale required. If the order is accepted, it is entered on to the Sage database or in related to Amazon orders will be polled via NetIX Software into the Sage data base and processed accordingly. Should the order not be acceptable, the customer is contacted and informed.
3.	Communications to the customer are by phone, post, or e-mail as necessary
4.	Each order must be accompanied by a Purchase Order or Reference number/identifier
5.	Any changes made to the order by the customer are noted in the Sage system.
6.	As part of the enquiry follow-up process, the customer may be contacted.
7.	Once the order is fulfilled a dispatch note and invoice are raised that shall be sent to the customer via email or other manners that will enable both the customer and the organization to track the shipment to it final destination in-line with customers' requirements. This process does not apply where orders are delivered via Amazon in relation to Fulfilled by Amazon (FBA) since Amazon undertakes the dispatching direct and invoicing via its own platform, the Company will be able to track order process via its Seller Central account with Amazon. Except as previously stated in relation to Amazon all dispatch notes and invoices shall have the lot and batch number of the product being released to allow for traceability. Traceability via Amazon is tracked via unique Amazon customer order number that is obtained from each Amazon sales order that can be tracked via Seller Central. Ref MDTi Ref00007.2.2 QM v 1.2 flow chart.
8.	Following a sale, the customer may be diarized to be followed up within an appropriate time frame.

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7.3	***Design and development***
7.3.1	***Design and development planning***
Summary of Requirements	The organization shall document procedures for design and development.
7.3.2	***Design and development planning***
Summary of Requirements	Whenever the Organisation undertakes any activity falling within this category it must ensure that there is effective management control of all aspects and stages of the work be planned and controlled. Such controls must determine and address (with documented procedures): Design of packaging and changes to initial CAD drawings before sign-off come under this section. a) Stage reviews of development and design, b) The identification of authorities and responsibilities for design and development, c) Product and planning review procedures, d) The establishment of effective communications, e) Review, verification, validation and design transfer activities that are appropriate at each stage, f) The methods to ensure traceability of design and development outputs to design and development inputs g) The resources needed, including necessary competence of personnel Planning output shall be documented and updated as appropriate, as the design and development progresses (4.2.3)
7.3.3	***Design and development inputs***
Summary of Requirements	All product inputs must be defined, recorded (see 4.2.5) and reviewed. Product inputs must be clear and unambiguous and may relate to some or all of the following: a) Functional and performance and safety requirements according to the intended use b) All relevant statutory and regulatory requirements c) Information derived from previous similar designs d) All other requirements essential for design and development e) Outputs of risk management (7.1) Inputs to be reviewed for adequacy and approved.
7.3.4	***Design and development outputs***
Summary of Requirements	Prior to its release to production, the customer or any third party, all design and development must fulfil the following stringent criteria in order to ensure that: a) The design output meets the input requirements

	b) Product acceptance criteria has been met c) The design output provides sufficient information for purchasing and production and service procedures d) The characteristics of the product that are essential for its safe and proper use are specified Records of outputs shall be maintained (4.2.5)

7.3.5	***Design and development review***
Summary of Requirements	Throughout the design and development processes the Organisation must ensure that systematic reviews are carried out and documented. These reviews must address the ability of the output to meet the established performance criteria, identify any problem areas and propose appropriate follow-up actions to the management and/or the customer. Specialist personnel to be included in review (5.5.1 and 6.2.1).
7.3.6	***Design and development verification***
Summary of Requirements	Formal verification that the design and development output meet the input requirements must be carried out and documented. Refer to Sections 7.3.1 and 4.2.4 and 4.2.5 of this Quality Procedures Manual.
7.3.7	***Design and development validation***
Summary of Requirements	Formal validation that the product meets the requirements relating to its intended use must be carried out and documented. (7.3.1) prior to delivery or implementation of the product – records of the results to be maintained (4.2.5) As part of design and development validation, the organisation shall perform clinical evaluations and/or evaluation of performance of the medical device as required by national or regional regulations.
7.3.8	***Design and development transfer***
Summary of Requirements	The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded (see 4.2.5).
7.3.9	***Control of design and development changes***
Summary of Requirements	All changes to the design and development, initiated or resulting from whatsoever source must be controlled, evaluated and approved prior to their implementation. Records of all such activities must be kept. A design review/sign off form is available (appendix 4).
7.3.10	***Design and development files***
Summary of Requirements	The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include, or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

	STATEMENT/PROCEDURE
1.	This section (7.3.1 - 7.3.5) is not generic to the nature of the Organization's current business activities or processes other than changes to the original design of the product in order to make it a fully commercially viable product. The organization does not undertake the initial design of products since this is an NHS function. Should this situation change, by customer requirement or for any other reason, appropriate procedures will be developed and introduced. 7.3.6 and 7.3.7 are relevant. Upon formal acceptance of taking any product, MDTi must have an acceptable CAD drawing or fully dimensional drawing along with a prototype if applicable. Any testing data prior to MDTi accepting the product to manufacture must be passed to MDTi.
2.	A design and development file for each medical device type or medical device family will be maintained, this file shall be commonly known as a 'Project file'. Each file shall include, or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.
3.	CAD copies along with any prototype shall be transferred to an approved sub-contractor in order to undertake manufacturing under the permission of the Organization.
4.	The Management Review process continuously monitors this situation.

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7.4	***Purchasing***
7.4.1	***Purchasing process***
Summary of Requirements	The organisation shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a) based on the supplier's ability to provide product that meets the organization's requirements; b) based on the performance of the supplier; c) based on the effect of the purchased product on the quality of the medical device; d) proportionate to the risk associated with the medical device. Therefore, the suppliers of all such products and materials must undergo an approval process based on their ability to supply based on the organisation's requirements and their performance must be regularly monitored. Evidence of these activities must be kept. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained
7.4.2	*Purchasing information*
Summary of Requirements	Care must be taken to ensure that when orders are placed for quality critical products and materials such orders include a full description of the requirements. This requirement may be discharged by the provision of drawings, technical specifications, qualifications and other Quality Management System based criteria. Include where appropriate: a. requirements for approval of product, procedures, processes and equipment b. requirements for qualifications of personnel c. QMS requirements The organisation shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. To the extent required for traceability given in 7.5.9, the organization shall maintain

	relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).
7.4.3	*Verification of purchased product*
Summary of Requirements	The organisation shall establish and implement the inspection of other activities necessary for ensuring that purchased product meets specified purchase requirements.

	STATEMENT/PROCEDURE
1.	A regularly updated List of Approved Suppliers and Critical Sub-contractors is maintained. New suppliers and sub-contractors are only added to the list when their performance has proved satisfactory. All new suppliers must complete the Suppliers Evaluation questionnaire (appendix 3) and will be ranked against criteria set out in appendix 3A at review meetings. Key(critical) Sub-contractors must be compliant to ETI base code by 2022.
2.	New suppliers and sub-contractors are originally selected based on several criteria, that may include: 1. Quality 2. Availability 3. Historical supply performance 4. Published technical data 5. Evaluation of previous work 6. Customer's requirements 7. ISO 9001 status 8. Ability to supply to British/European/International Standards 9. Compliance with ETI base code All critical suppliers for product must accept to amortize tooling if requested to be considered as a manufacturing partner. They must also agree to regular meetings whilst working on the project and to give regular updates. They must be prepared to be used within PR activities both internal and external to their manufacturing base. Critical suppliers should provide all technical information, product make-up, flow charts, FMEA's, control plans.
3.	All orders are placed on suppliers on the approved list unless otherwise approved by the CEO.
4.	Orders are raised for specific requirements and/or to maintain previously determined stock holding levels.
5.	Orders are documented on a numbered purchase order and recorded on Sage software and a paper copy held on file. These are then issued by fax, e-mail or letter. In the case of a fax or email, they are then followed up in the post with a hard copy.

6.	All items received into the Organization from suppliers are sample checked to ensure that there are no visible signs of damage and against the order for quantity, product type and version and batch number.
7.	Items with damage to the outer container are opened and the contents checked for damage prior to the Delivery Note being signed and accepted. Supplier delivery note shall contain the following statement or similar to ensure quality check has been undertaken by them prior to receipt into the organization, "***It is certified that the whole of the goods detailed have been inspected and tested in accordance with the conditions and requirements of the relevant contract. Unless stated otherwise conform in all respects to the specification(s) relevant thereto"***.
8.	If this is not possible the Delivery Note is marked **"Goods Not Checked"**.
9.	Incidents of defective or damaged items are recorded on the Delivery Note and a non-conformance letter or return note raised and sent to the supplier.
10.	Whenever applicable all deliveries are cross checked against the order by the member of staff who originally issued the order; discrepancies are notified to the supplier
11.	Should there be a requirement for verification at the supplier's premises, by either the organization or the customer's representative, then the details of the verification processes to be used are described in the purchasing documents.
12.	Re-evaluation of critical suppliers should be undertaken should one of the following criteria be triggered that will affect the product or quality of the service the company provides: • Change in raw material being supplied • Change in supplier's ISO status • Number of supplier corrective actions (SCAR) • Return rate of products • On-time delivery ***Re-evaluation of critical suppliers should be undertaken at least once every 3 years.***
13.	Suppliers to remain approval will in relation tom point 12 provide evidence to MDTi at supplier's review meeting validation evidence of equipment performance, controls, monitoring, and instrumentation are capable of operating within the parameters prescribed for the process equipment to produce the quality of product sub- contracted so that product consistently meets predetermined specifications for quality and function. Sub-contractor's information will be sampled and such sample documentation documented for MDTi's records.

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7.5	***Production and service provision***
7.5.1	***Control of production and service provision***
Summary of Requirements	The organisation shall plan and carry out production and service provision under controlled conditions as the availability of information that describes the characteristics of the product and the availability of work instructions, reference materials, and reference measurement procedures and other documented procedures. The Organisation must also ensure the availability of suitable production equipment, including measuring and monitoring equipment. Release, delivery and post- delivery requirements must also be addressed including the implementation of defined operations for labelling and packaging. Traceability by batching must be shown (7.5.9). The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

	STATEMENT/PROCEDURE
1.	All commercialization, marketing and work is carried out using the skills, experience and training of the respective staff, and as a result, written work instructions are not considered necessary (beyond those described in this Quality Procedures Manual Section 4.2.3, 7.2), Staff may however make reference to the technical specifications and delivery/supplier partners facilities wherever appropriate.
2.	Consequently, detailed work instructions describing product commercialization beyond those already described in this Quality Procedures Manual are not considered necessary.
3.	A dispatch manual is maintained separately that describes the pertinent individual characteristics to specific customers' requirements, i.e. labelling, codes

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7.5.2	***Cleanliness of Product***
Summary of Requirements	The organization shall document requirements for cleanliness of product or contamination control of product if: a. product is cleaned by the organisation prior to sterilisation and/or its use, b. product is supplied non-sterile to be subjected to a cleaning process prior to sterilisation and/or its use, c. product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use, d. product is supplied to be used non-sterile and its cleanliness is of significance in use, e. process agents are to be removed from product during manufacture. *If products are cleaned in accordance with a or b above, the requirements contained in 6.4.1do not apply prior to the cleaning process.*

	STATEMENT/PROCEDURE
1.	All products are supplied to customers as non-sterile. Instructions for cleaning or sterilization where applicable are documented within user's instruction for use.

7.5.3	***Installation activities***
Summary of Requirements	The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5).

	STATEMENT/PROCEDURE
1.	***The organization nor any of its suppliers undertake the installation of any medical devices produced offered by the organization***. Where a requirement for product installation to be perform by the customer or an external party the organization provides documented requirements by way of the 'instructions for use' for medical device installation and verification of installation.

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7.5.4	***Servicing activities***
Summary of Requirements	If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained.

	STATEMENT/PROCEDURE
1.	***Not applicable***: The organization nor any of its suppliers provide servicing of medical devices that it produces.

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7.5.5	***Particular requirements for sterile medical devices***
Summary of Requirements	The organization shall maintain records of the sterilization process parameters used for each sterilization batch. Sterilization records shall be traceable to each production batch of medical devices.

	STATEMENT/PROCEDURE
1.	***Not applicable***: The organization nor any of its suppliers undertake or supply medical devices that require sterilization. Sterilization is outside the scope of the business activities.

7.5.6	***Validation of processes for production and service provision***
Summary of Requirements	The organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organisation shall establish arrangements for these processes including as applicable: a. defined criteria for the review and approval of the processes b. approval of equipment and qualification of personnel c. use of specific methods and procedures d. requirements for records (4.2.5) e. revalidation The organisation shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.

	STATEMENT/PROCEDURE
1.	***Not applicable*:** This requirement is outsourced to the approved key supplier and assurance provided by them that they have the capabilities to meet this requirement on behalf of the organization when undertaking manufacturing of products.

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7.5.7	***Particular requirements for validation of processes for sterilization and sterile barrier system***
Summary of Requirements	The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate. Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

	STATEMENT/PROCEDURE
1.	***Not applicable*****:** The organization does undertake any sterilization activities or provide any sterile barrier systems.

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7.5.8	***Identification***
Summary of Requirements	The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

	STATEMENT/PROCEDURE
1.	The quality status of the product within the process is identified as follows: - Already packaged products are quality ASSURED for release by the supplier and quality controlled through random sampling by the organization. Details of sampling are recorded on document 'MDTi procedure for products into Supply Chain ref MDTi/8.2.4.1 Unpackaged products are inspected and released when packed by MDTi. Any products that fail inspection or have been justifiably rejected by the customer are placed in a separate box clearly labelled 'NON-CONFORMING OR SUSPECT PRODUCT'.
2.	All products received from Critical Subcontractor shall be accompanied by a delivery note that shall indicate that product has been inspected and tested in accordance with the conditions and requirements of the relevant contract UDI/UDPI
3.	In accordance with MDR each product category will have its own UDI (Barcode) established through GS1. The UDPI shall be that of the Batch/Lot number and date of manufacturing of products received in.
4.	To ensure that quality status of the product is monitored and maintain no product is released without having both the UDI/UDPI on packaging.

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7.5.9	***Traceability***
7.5.9.1	***General***
Summary of Requirements	The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5).
7.5.9.2	***Particular requirements for implantable medical devices***
Summary of Requirements	The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements. The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5).

	STATEMENT/PROCEDURE
1.	Each supply is issued with UDI-DI and a unique lot/batch number and date of manufacturing by the critical subcontractor. This identification detail is traceable through contract manufacturers batch numbers and recorded on packaging and delivery paperwork. Process Maps are available in the Green Process folder for: 1 Batch Control. 2 Checking and acting on medical device alerts for MHRA, FDA & Med safe. *Vigilance and Post market surveillance reporting for adverse Incidents and Near Accidents for EEC, US and New Zealand are found in Section 6 of each product technical folder.*
2.	Clause 7.5.9.2 is Not Applicable since the organization does not manufacturer or supply implantable medical devices.

7.5.10	***Customer property***
Summary of Requirements	The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5). Customer property can include Intellectual Property or confidential health information.

	STATEMENT/PROCEDURE
1.	Customer data or product returns once paid for are considered as Customer Property. The Company at no time receives any customer health data. All customers' data will be maintained in-line with its GDPR policy and procedures. Any product return from a customer will be offered an immediate replacement or refund. The company will investigate reason for the product return in-line with it is non-conformance procedures. The Management Review process monitors this situation and, should the circumstances change, procedures should be introduced to address and comply with the requirements of the Standard as summarized above.

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7 - PRODUCT REALISATION

7.5.11	***Preservation of product***
Summary of Requirements	Procedures must be established and maintained in order to ensure that adequate and suitable materials are available to identify, handle, protect and store products, during their manufacture and subsequent storage and delivery to preserve conformity of product. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).

	STATEMENT/PROCEDURE
1.	Packed and unpacked products are stored in well-lit weatherproof building.
2.	All products received from Subcontractors are identified by a unique LOT/batch information and barcode (UDI-DI) on the packaging, UDPI is represented by a label LOT/batch codes with date of manufacturing are traceable by the contract manufacturer.
3.	Preservation of product is communicated to critical subcontractors in accordance with the conditions and requirements of the relevant contract in place.

QUALITY PROCEDURES MANUAL

7 - PRODUCT REALISATION

7.6	***Control of monitoring and measuring devices***
Summary of Requirements	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5); b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5); c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.5).

	STATEMENT/PROCEDURE
1.	***Not applicable***: The Organization no longer offers the 'Uflow meter' on the market.

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8	***Measurement, analysis and improvement***
8.1	***General***
Summary of Requirements	The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed. a) demonstrate conformity of product; b) ensure conformity of the quality management system; c) maintain the effectiveness of the quality management system. The Organisation must formally define the activities needed to measure and monitor product improvement and conformity. This shall include the determination of applicable methods, including statistical techniques, and the extent of their use.

	STATEMENT/PROCEDURE
1.	The Organization monitors, measures, analyses and improves its processes in order to: 1. Demonstrate conformity of product and its activities 2. Ensure conformity to the Quality Management System 3. Maintain the effectiveness of the Quality Management System
2.	The Organization and its subcontractors continuously employ statistical analyses techniques to measure and monitor product improvement and conformity. These techniques may relate to: 1. Data analysis 2. Performance testing 3. Defect analysis 4. Customer complaints and communications 5. Market performance
3.	Information obtained by such statistical analyze may relate to: 1. Trends 2. Operational performance 3. Levels of customer satisfaction 4. Overall effectiveness and efficiency Note: National or regional regulations might require documented procedures for implementation and control of the application of statistical analysis.

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.2	***Monitoring and measurement***
8.2.1	***Feedback***
Summary of Requirements	As one of the measurements of the QMS, the organisation shall monitor information relating to whether the organisation has met customer requirements. The methods for obtaining and using the information shall be documented The organisation shall establish a documented procedure for a feedback to provide early warning of quality problems and for input into the corrective and preventive action processes; data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.

	STATEMENT/PROCEDURE
1.	Those members of staff who make regular contact with customers as part of their day-to-day duties carry out routine monitoring of the levels of customers perceived satisfaction in the products supplied.
2.	Customer satisfaction is measured by the following parameters: - Customer complaints Customer Surveys Customer Feedback Re-ordering product Sales turnover activity
3.	Staff feedback is sought on any repacking/packing of product. This will include feedback from critical subcontractors when processing product.
4.	Feedback is encouraged and the results recorded and analyzed at Management Review, as detailed in Section 5.6.

8.2.2	***Complaint handling***
Summary of Requirements	The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for: a) receiving and recording information; b) evaluating information to determine if the feedback constitutes a complaint; c) investigating complaints; d) determining the need to report the information to the appropriate regulatory authorities; e) handling of complaint-related product; f) determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Complaint handling records shall be maintained (see 4.2.5).
	STATEMENT/PROCEDURE
	The Organization shall follow ISO 10002:2004(e) Customer satisfaction - Guidelines for complaints handling in organization, copy on server and hard copy placed in this manual section marked up 'Standard'.
	Organization personnel will complete Annex D 'Complaint follow-up form' contained in the copy of ISO 10002:2004 prior to determining whether a complaint warrants the raising of a nonconformance form or undertaking corrective actions or preventive actions (CAPA). This record shall be retained for audit purposes and improvement to management system.
	A nonconformance should only be raised once the complaint assessment has been completed and only if the assessment concludes the complaint is **high** or **medium** risk of being repeated. The table below should be used to determine the raising of a nonconformance along the appropriate CAPA.

Compliant	**High**	**Medium**	**Low**
Severity			
Complexity			
Impact			

1.	The process flow chart on page 19 (Annex F) of ISO10002 should be followed when handling customers' complaints and information recorded on form Annex D.
2.	The procedure allows a flexible approach to be applied and encourages resolution of complaints. Whilst still providing for a more formal investigation should the need arise.
3.	The Organization recognizes the value of direct communications with Customers and regards constructive comments, suggestions and complaints as part of the process of maintaining and developing its activities. MDTi shall investigate all complaints and incidents thoroughly and promptly.
4.	Any complainant who remains dissatisfied with the outcome of the investigation has the right to refer to an independent review panel.
5.	Complaints about the Organization and the products it provides should be dealt with as follows: Staff are encouraged in conjunction with management to deal with concerns and request for Information to which they can provide an immediate response. Where this is not possible, the Organization must acknowledge receipt of a complaint and offer to discuss the matter within 3 working days. Agree with the complainant the way they would like their complaint investigated (Local/ Formal) and an acceptable timeframe. Investigate the complaint in a full and objective way. Write to the complainant on completion of the investigation, explaining how it has been resolved, what appropriate action has been taken and reminding them of their right to take the matter to the Office of Fair Trading or any other particular government agency based upon the jurisdiction of where compliant is raised.
6.	Keep a record of all complaints, the results of investigations, the lessons learned, and any actions implemented as a result.
7.	**Complaints across boundaries:** Where complaints against the Organization is part of a wider complaint, MDTi staff will work with other Organizations to ensure a single coordinated response.
8.	The Organization is committed to ensuring that all staff and customers are supported during the complaints process by: • Ensuring fairness, openness and impartiality during complaints investigations. • Ensuring that all staff have an opportunity to comment on any

	responses made. • Accepting where something has gone wrong and apologise for it.
9.	**Monitoring and Reporting:** The Quality Manager will produce a report to the organization annually detailing the number of complaints and causes with an analysis of the issues raised, recommendations to address the issues, actions taken as a result of the recommendations and evidence that the actions have been implemented. In addition, the report should contain: • Specify the numbers of complaints received. • Identify the subject matter of those complaints. • Whether upheld or not. • Whether referred to an independent review agency. • A narrative of significant issues throughout the year.
10.	During the investigation of a complaint, if it is identified that there is an 'incident' staff will follow the steps in Incident Reporting as outlined in MEDDEV 2 12-1 rev. 8 Vigilance

8.2.3	***Reporting to regulatory authorities***
Summary of Requirements	If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.5)
	STATEMENT/PROCEDURE
1.	The Organisation follows the guidelines (**MDR 2017/745**) Medical Devices Vigilance system in order to meet the applicable regulatory requirements for notification of complaints that meet specified reporting of adverse events or incidents. This procedure summarizes when this should be done.
2.	The Organization must submit an initial incident to the **NCA** (**National Competent Authority**) for recording and evaluation. A report must lead to a final report unless the initial report and final report are combined into one report. **Not every** INCIDENT report will lead to a corrective action.
3.	As a rule, there should be a pre-disposition to report than not to report in case of doubt on the reportability of an INCIDENT.
4.	Incidents that occur outside of the EEA, Switzerland and Turkey do not lead to a Field Safety Corrective Action relevant to these geographical areas do not need to be reported.
5.	**Timescale for reporting of an INCIDENT**: Upon becoming aware of an event and on one of the Organizations products may have caused or contributed to the event, the Organization must determine whether it is an INCIDENT. The following timeline applies: • Serious public health threat: IMMEDIATELY • Death or unanticipated serious deterioration in state of health: IMMEDIATELY after the Organization establish a link between the produce and the event but **not less** *than **10** elapse calendar days.* • Others: IMMEDIATELY after the Organization establishes a link between the produce and the event but **not less** *than **15** elapse calendar days.* If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the Organization must submit a report within the timeframe for that type of INCIDENT.
6.	**Criteria for INCIDENTs to be reported**: Any event which meets **all** three of the below is considered as an incident and must be reported to relevant NCA:

	A: *An event has occurred*, a malfunction or deterioration in the characteristics or performance of the product with its *Intended Purpose* with the instructions for use. **B:** *Device is suspected to be a contributory cause of the incident,* assessing the link between the product and the INCIDENT taking into account: • Opinion, based upon evidence, of healthcare professionals. • The results of the Organization's own preliminary assessment of the INCIDENT. • Evidence of previous similar INCIDENTs. • Other evidence held by the Organization. **C:** *The event led, or might have led, to one of the following outcomes,* • Death of a patient, User or other person • Serious deterioration in state of health of a patient, User or other person A serious deterioration in state of health can include (but not limited) a) Life-threatening illness b) Permanent impairment of a body function or permanent damage to a body structure c) A condition necessitating medical or surgical intervention to prevent a) or b). d) Indirect hard as a consequence of an incorrect diagnosis.
7.	**Form for reporting INCIDENTs:** *A copy of report form manufacturer's incident report can be found at ANNEX3 of MEDD 2.12-3 Rev8*. Persons reporting INCIDENT should take a photocopy of this form (pages 40 to 44) and complete all relevant details, the form will need to be checked and *signed off by the Organization's clinical lead* manager prior submitting to the appropriate NCA. A copy of the submitted document is to be always kept on file.

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.2.4	***Internal audit***
Summary of Requirements	Internal Quality Audits are a fundamental requirement of this International Standard. They must be conducted at regular pre- determined intervals and, as a minimum, be undertaken twice annually, and address the: a) Degree to which the Organisation conforms to the requirements of the Standard b) Level of conformance of the Organisation's activities to the Quality Management System as set out in this Quality Procedures Manual Documented procedures must be maintained covering all of the procedures relating to Internal Quality Audits. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. Refer to Section 8.5.2 of this Quality Procedures Manual.
	STATEMENT/PROCEDURE
1.	A Quality Audit programme is maintained by the Quality Manager, ensuring that every section of the Quality Management System is verified at least once annually.
2.	More frequent Quality Audits may be organised by the Quality Manager, depending on customer satisfaction see section 8.2.
3.	Internal Quality Audits are carried out according to the following procedures:
4.	At the beginning of each quarter, the Quality Manager consults the Quality Audit program and establishes which, if any, parts of the Quality Management System are to be audited during the coming month.
5.	At times a trained member of staff, independent of the activity to be audited, is appointed by the Quality Manager to undertake the audit. It is stressed that audit must be impartial from the person undertaking the activity. The audit is not allowed to audit their own activities.

8.2.4	***Internal audit*** *(Continued)*
6.	The auditor refers to the Quality Procedures Manual and determines the activities to be audited.
7.	The auditor selects a representative number of records to be audited on a random basis.
8.	The auditor advises any personnel concerned that a Quality Audit is being undertaken and answers any questions they may have regarding the audit.
9.	The auditor examines the records selected in order to determine whether the activities identified above have been carried out correctly.
10.	The auditor keeps a record of the process and the findings of the Quality Audit.
11.	The Quality Audit record and all other documents relating to internal audits are passed to the Quality Manager.
12.	The Quality Audit record and all other documents relating to internal Quality Audits are retained for inspection by the external 3rd party auditor for review at the annual external Quality Audit.
13.	All issues arising from the internal Quality Audit requiring immediate attention are discussed with the appropriate personnel and a record kept on a Quality Audit Report or Management Information Report as appropriate.
14.	The Quality Manager ensures that the Quality Audit results are discussed at the next Management Review.

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.2	*Monitoring and measurement (Continued)*
8.2.5	***Monitoring and measurement of processes***
Summary of Requirements	Procedures must be established and maintained to measure and monitor the Quality Management System processes in order to ascertain the extent to which they meet customer requirements and satisfy their intended purpose.

	STATEMENT/PROCEDURE
1.	Monitoring and measurement of processes is achieved by implementation of the procedures set out in Sections 8.2.4 (Internal Audit) and 5.6 (Management Review).
2.	Documents used to facilitate the monitoring and measurement of processes include but are not limited to: 1. Quality Audit records 2. Customer feedback records 3. Non-conformance records 4. Management Review records

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.2	*Monitoring and measurement (Continued)*
8.2.6	***Monitoring and measurement of product***
Summary of Requirements	Procedures must be established and maintained to monitor and measure the characteristics of the product against the acceptance criteria and these activities must be documented. Control procedures must ensure that product is not released until the acceptance criteria have been met. The organisation shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements (7.1) and documented procedures (7.5.1) Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorising release of product. Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed.

	STATEMENT/PROCEDURE
1.	All product testing is undertaken by product manufacturers or contracted to third party contractors
2.	It is policy of the organization that no products are released on quality concession
3.	Under the manufacturing contracts agreed, quality control tests are agreed
4.	When products are packed by the organization a final quality inspection is undertaken, and sampling certification is recorded and signed off by the person authorizing release of product.

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.3	***Control of non-conforming product***
8.3.1	***General***
8.3.2	***Actions in response to nonconforming product detected before delivery***
8.3.3	***Actions in response to nonconforming product detected after delivery***
8.3.4	***Rework***
Summary of Requirements	The organisation shall ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organisation shall deal with nonconforming product by one or more of the following ways: a. by taking action to eliminate the detected nonconformity b. by authorising its use, release or acceptance under concession c. by taking action to preclude its original intended use or application The organisation shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorising the concession shall be maintained. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organisation shall take action appropriate to the effects, or potential effects of the nonconformity. If product needs to be reworked (one or more times). The organisation shall document the rework process in a work instruction that has undergone the same authorisation and approval procedure as the original work instruction. Prior to the authorisation and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (4.2.5 and 7.5.1)

	STATEMENT/PROCEDURE
1.	Products not meeting the required specifications and all other activities not meeting the requirements of the Quality Management System or agreements with customers are quickly investigated. This is the responsibility of the Company Director.
2.	All products found to be faulty or unsuitable are clearly identified and segregated. Quarantine areas are maintained at the subcontractor manufacture site and the Kace building also has a defined storage where quarantined product is stored.
3.	The occurrence is investigated to establish its root cause and the appropriate corrective action
4.	All details of Complaints, non-conforming products and service are recorded on an MDTi Non-conformance Report and actioned appropriately.
5.	It is a manufacturing requirement that any reworked product must meet all product specification requirements
6.	When nonconformity is detected after delivering the product, actions must be taken relevant to the nature of the nonconformities. When a nonconforming product is re-processed, it must be re-validated to ensure that it meets the requirements (customer's or regulatory).
7.	All staff are responsible for reporting on a nonconformity. Staff must fill out Nonconformance Report with the details of the non-conformity. Check any previous production to ensure conformity. Follow recall process if any defective product is released to customers. Move all affected goods to the designated quarantine area and attach a "non-conforming goods" label. Investigate the source of the problem and correct it before resuming supply. Staff to determine what action should be taken with nonconforming goods - rework, scrap, etc., If the scheduled delivery date is affected, inform the customer Reworked items will be checked as per normal inspection with doubled sampling rates. See corrective action for more details on what else needs to happen to address a nonconformity, i.e. actions to investigate and eliminate the root cause(s). When root cause has been addressed and verification of effectiveness has been completed, manager to review and sign-off NCR as closed.

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.4	***Analysis of data***
Summary of Requirements	Data received and held by the Organisation relating to customer satisfaction levels, product conformance requirements and any trends that may introduce opportunities for preventive action must be securely held and analysed for consideration during Management Review. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product, including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).

	STATEMENT/PROCEDURE
1.	The following data (generated as a result of monitoring and measurement) is analyzed to identify trends and opportunities for preventive and/or improvement actions: 1. Feedback (8.2.1) 2. Conformity to product requirements (7.2.1) 3. Product and/or service trends 4. Results of internal Quality Audits as a measurement of the effectiveness of the Quality Management System 5. Non-conformance records 6. Suppliers
2.	The analyzed data is presented as critical input into the Management Review process set out in Section 5.6.
3.	Analyzing the areas in Point 1 to identify trends and patterns in the Company's processes to verify the continuing suitability and control of

	the effectiveness of its QMS and by maintaining improvement the data analysis that relate to the issues having relevance to the performance of the company's QMS. These issues will be inputs for data analysis. The requirements for data resources are the controls that were suggested throughout the standard, i.e.: • Human resources • Work environment • Substructures • Product quality planning • Control of product and processes • Risk control performances • Validation and verification, etc. From these issues, we can identify which processes trigger data that can be analyzed. The evaluation of each data will give us an answer to the requirements above. The analysis of the data will allow us to detect trends and patterns occurring that require attention.

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.5	***Improvement***
8.5.1	***General***
Summary of Requirements	The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review.

	STATEMENT/PROCEDURE
1.	The effectiveness of the Quality Management System is continually reviewed and improved through the Management Review process set out in Section 5.6 and by: 1. The application of the Quality Policy 2. The application of the Quality objectives 3. Quality Audits 4. Analysis of data 5. Corrective and preventive actions 6. Circulation of Management Review Minutes

QUALITY PROCEDURES MANUAL

8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.5.2	***Corrective action***
Summary of Requirements	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; f) reviewing the effectiveness of corrective action taken. Records of the results of any investigation and of action taken shall be maintained (see 4.2.5).
8.5.3	***Preventive action***
Summary of Requirements	Documented procedures must be established and maintained to address: a) Identifying potential non-conformities and their causes b) Evaluating the need for action to prevent occurrence of nonconformities c) determining and implementing action needed d) Recording and reviewing of investigations and actions taken e) Reviewing preventive action taken and its effectiveness

	STATEMENT/PROCEDURE
1.	As a fundamental component of their role, senior management is responsible for identifying situations within the Organization's activities that may create non-conformances and address any risks and opportunities as a consequence of any non-conformities.
2.	Whenever such a situation is identified, preventive action is formulated and applied.
3.	All such action is recorded on a Customer Complaint Form or Non-

	Conformance Report and its cause and effect is subject to Management Review in addition to routine monitoring.
4.	The action taken to correct any non-conformances is recorded on the Customer Complaint Form or Non-conformance Report.
5.	An investigation is undertaken to determine the cause of the non-conformance.
6.	The preventive action taken to prevent recurrence of any such activities is similarly recorded.
7.	The collective actions taken to prevent recurrence of non-conformance, and those records and reports generated, are regularly reviewed at Management Reviews to identify any trends and to determine the effectiveness of preventive measures taken.
8.	Revised procedures are developed and implemented as considered appropriate and are reviewed accordingly.

QUALITY PROCEDURES MANUAL

APPENDICES