QUALITY PROCEDURES MANUAL

QUALITY POLICY

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

The Organisation operates a Quality Management System that operates to 13485:2016 certification, including specific to the commercialisation 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 Organisation complies with all relevant statutory and regulatory requirements. Promote awareness of all regulatory requirements to pertinent stakeholders, in particular, suppliers. The Organisation 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: _____ **Name:** _____ **Date:** 20/4/2021