MedTech

City Industrial Center,

Unit A,

Our Town, USA

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DOCUMENTS and RECORDS

MedTech Documented Information – Contents

Qty	Documents and Records	No. of Pages
1	QMD-01 Quality Manual	8
1	F-424-001 List of Documented Information	2
1	Internal Audit Master Schedule	1
1	P-500 Management Responsibility Procedure	2
1	A-530-001 Quality Policy and Strategic Direction	1
1	P-710 Planning of Product Realization	2
1	F-710-001 Risk and Opportunity Worksheet	1
2	F-710-002 Project Planning Worksheet	3
1	P-720 Customer Related Processes Procedure	3
1	F-720-001 Client Assessment Report	1
2	F-720-002 MedTech Quotation / Proposal	2
1	P-740 Purchasing Procedure	3
1	F-740-001 List of Approved Sources	1
3	F-740-002 MedTech Purchase Order / Amended Purchase Order	3
1	F-740-003 External provider Problem Log Form	1
1	P-852 Corrective Action Procedure	2
1	F-821-001 Customer satisfaction survey	1
1	R-820 Register of Improvement Action Reports - NCR-CAR	1
1	F-852-001 Corrective Action Request Form (CAR)	1
1	NCR – Section 1 Corrective Action Requests	1
1	CAR – Section 2 Corrective Action Requests	1
1	P-560 Management Review Procedure	2
1	F-560-001 Management Review Meeting Agenda	1
1	F-560-002 Minutes of Management Review	2

Section 01 Scope or the Quality Management System

To determine and establish the scope of the Quality Management System, MedTech determined the roles it undertakes as a provider of medical devices and considered the products and services of the company.
The scope is available and maintained as documented information stating the products and services covered by the QMS.

Due to the nature of the business, MedTech applies all the requirements of ISO 13485:2016 when they are applicable within the determined scope of the QMS.

Conformity to ISO 13485:2016 may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

In the event that any requirement is not applicable at MedTech, justification for any instance where a requirement cannot be applied is documented.

Section 02 References

a. Normative reference – ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary.

b. Definitions Applicable definitions are included in documented procedures and instructions at par 3.0 to enhance the understanding of the process.