




File	QUALITY MANAGEMENT SYSTEM RMT
Scope of QMS	<b>DESIGN, DEVELOPMENT &amp; MANUFACTURING OF INTRAVASCULAR DEVICES (MICROSPHERES)</b>
Domain	QUALITY ASSURANCE
Document Name	MASTER INDEX OF DOCUMENTS
Document Type	CONTROLLED LIST
Document No.	QA.IND.01
Language	EN
Version	2.0
Document owner	REVIVE MEDITECH PVT LTD.
Address	BUILDING 2A, W1 STREET, RAWAT INDUSTRIAL ESTATE, ISLAMABAD, PAKISTAN (46220)
Confidentiality level	MODERATE
Coming into effect	10 <sup>th</sup> February, 2025
Purpose and goal:  This document is a part of the QUALITY MANAGEMENT SYSTEM folder of REVIVE MEDITECH PVT LTD. compiled for compliance of ISO 13485:2016 requirements.	

ROLE	DESIGNATION	NAME	DATE	SIGNATURE
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REVISION HISTORY

Revision	Status	Date	Description of Change
1.0	OBSOLETE	16-09-2024	Initial version
2.0	APPROVED	10-02-2025	Design updates (design version 2 activities initiated i.e. design documents updated)

NOTE:

Document Status	Description	Marking Type	Document Type
DRAFT	Documents under creation, revision or review	In document background	Electronic
APPROVED	Approved documents in electronic Document Management System	In revision history table	Electronic
MASTER COPY	Approved documents in Quality Manager Office	Stamped	Physical
CONTROLLED COPY	Approved documents sent to concerned department for reference	Stamped	Physical
OBSOLETE	Documents replaced by new revisions	Stamped/Moved to archive	Physical/Electronic

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## 1 PURPOSE

The purpose of the “Master List of Documents” of **Revive Meditech Pvt Ltd.** Is to provide a comprehensive, organized, and easily accessible overview of all controlled internal documents related to the organization's quality management system, ensuring efficient management and compliance.

## 2 SCOPE

**Revive Meditech Pvt Ltd.** “Master List of Documents”, outlines the scope of the QMS, including all relevant policies, procedures, work instructions, records, and other documentation needed to manage quality effectively, ensuring compliance and consistency.

## 3 RESPONSIBILITY

The responsibilities for creating and maintaining the **Master List of Documents** at **Revive Meditech Pvt Ltd.** shall be in accordance with the **SOP Document Control**.

The Top Management shall ensure that the “Master List of Documents” serves the following purposes:

- Consistency of Processes** - ensuring that all employees follow standardized procedures and use the latest approved versions of documents, leading to consistent quality outcomes.
- Regulatory Compliance** - maintaining a controlled and up-to-date list of documents to demonstrate compliance with ISO 13485 requirements and other applicable regulatory standards.
- Audit Readiness** - enabling efficient retrieval of relevant documents during internal and external audits, thereby streamlining the audit process.

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- Traceability and Accountability** - providing a verifiable trail of evidence that demonstrates adherence to ISO 13485 requirements, regulatory obligations, and internal quality policies.

#### 4 ABBREVIATIONS/DEFINITIONS

Documents Term synonymously used in procedures, work instructions etc.

QMS	Quality Management System
MD	Medical Device
TF	Technical File
FDA	Federal Drug Regulatory Authority
CAPA	Corrective and Preventive Action
PMS	Post-Market Surveillance
PMCF	Post-Market Clinical Follow-up
QA	Quality Assurance
QC	Quality Control
RMP	Risk Management Plan
UDI	Unique Device Identifier
NC	Non-Conformity
SOP	Standard Operating Procedure
RA	Regulatory Affairs
V&V	Verification and Validation
WI	Work Instruction
FRM	Forms
DHF	Design History File
DMR	Device Master Record
DHR	Device History Record

#### 5 PROCEDURES FOR MASTER LIST OF DOCUMENTS

In accordance with **SOP Document Control** of **Revive Meditech Pvt Ltd.** all Quality Management Systems shall follow a specific numbering scheme as outlined in this section.

##### 5.1 NUMBERING SCHEME OF DOCUMENTS

###### 5.1.1 Quality Management Scope Documents Numbering

QUALITY MANAGEMENT DOCUMENT NAME ABBREVIATIONS	
QMS	Quality Management System
RMT	Revive Meditech Pvt Ltd.
QMS.Pol.01	Quality Policy
QO	Quality Objectives
QM	Quality Manual
QS	Quality Scope
DHF	Design History File
MS	Microspheres

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### 5.1.2 Quality Management System Structure Documents Numbering

#### Abbreviations of Domains

Domain	ABBREVIATION
Admin	ADM
Procurement & Supply Chain	PSC
Storage & Warehousing	SWH
Human Resources	HR
Finance	FIN
Design & Development	DD
Quality Assurance	QA
Production	PRD
Quality Control	QC
Microbiology	MBL
Quality Management System Docs	QMS
Risk Management	RM
Regulatory Affairs	RA

#### Abbreviations of Type of Documents

DOCUMENT TYPE	ABBREVIATION
Policy	Pol
Standard Operating Procedure	SOP
Index	IND
Work Instructions	WI
Forms/Logs/Reports	FRM
Records	RR
List	LIS

#### Abbreviations of DHF Documents

DOCUMENT TYPE	ABBREVIATION
Product Realization	PR
User Input	UI
Use Specification	US
Design Input	DI
Risk Management Plan	RP
Risk Management File	RF
Design execution	DE

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Design Output	DO
Design Verification	DVR
Design Validation	DVL

Documents Numbering Criteria:

<b>Method 1: AA-BB-CC</b> (used for detailed controlled documents like SOPs, Quality Objectives, etc.)	
AA	Domain
BB	Type Of Document
CC	Document Serial Number
<b>Method 2: XX/YY.BB.CC</b> (used for product specific documents like TF & DHF)	
XX	File
YY	Project
BB	Type Of Document
CC	Document Serial Number
<b>Method 3: XX/SUBDOMAIN OR SOP.BB.CC.DD</b> (used for controlled templates & documents like work instructions, forms, records etc.)	
AA	Domain
BB	Type Of Document
CC	Document Serial Number
DD	Version Number

6 MASTER LIST OF QUALITY MANAGEMENT SYSTEM DOCUMENTS

Sr. No.	DOCUMENT NAME	DOCUMENT NUMBER	CURRENT VERSION
QUALITY MANAGEMENT SYSTEM			
1.	Quality Policy	QMS.Pol.01	1.0
2.	Quality Scope	QMS.QS.01	1.0
3.	Quality Manual	QMS.QM.01	1.0
4.	SOP Quality Objectives	QMS.SOP.01	1.0
5.	Quality Objectives	QMS/01.FRM.01.01	1.0
DOCUMENT MANAGEMENT			
6.	SOP Document Control	QA.SOP.01	1.0
7.	SOP Control of Records	QA.SOP.02	1.0
8.	Master Index of Documents	QA.IND.01	2.0
9.	List of External Documents	QA/01.LIS.02.01	1.0

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10.	Master Record File	QA/02.FRM.01.01	1.0
CHANGE MANAGEMENT			
11.	SOP Control of Change	QA.SOP.03	1.0
CHEMICAL MANAGEMENT			
12.	SOP Chemical Management	QA.SOP.04	1.0
MONITORING AND MEASURING EQUIPMENT			
13.	SOP Control of Monitoring And Measuring Equipment	QA.SOP.05	1.0
14.	SOP Maintenance	QA.SOP.06	1.0
15.	WI In-house Calibration	QA/05.WI.01.01	1.0
16.	Master Equipment List	QA/05.FRM.01.01	1.0
17.	Infrastructure Maintenance Plan	QA/06.FRM.01.01	1.0
18.	Equipment Maintenance Plan	QA/06.FRM.02.01	1.0
MONITORING AND MEASUREMENT			
19.	SOP Internal Audit	QA.SOP.07	1.0
20.	SOP Data Analysis	QA.SOP.08	1.0
21.	Internal Audit Plan	QA/07.FRM.01.01	1.0
22.	Internal Audit Checklist	QA/07.FRM.02.01	1.0
MANAGEMENT REVIEW			
23.	SOP Management Review	QA.SOP.09	1.0
NONCONFORMANCE MANAGEMENT			
24.	SOP Deviation Control	QA.SOP.10	1.0
25.	SOP Non Conformance of Product	QA.SOP.11	1.0
26.	SOP CAPA	QA.SOP.12	1.0
IDENTIFICATION			
27.	SOP-Identification, Acceptance Status & Traceability	QA.SOP.13	1.0
LOT RELEASE			
28.	SOP Lot Release	QA.SOP.14	1.0

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CUSTOMER FEEDBACK			
29.	SOP Complaint Handling	QA.SOP.15	1.0
30.	SOP PMS, Vigilance, and Customer Feedback	QA.SOP.16	1.0
HUMAN RESOURCE (HR)			
31.	SOP Human Resource Management	HR.SOP.01	1.0
32.	SOP Health & Safety	HR.SOP.02	
ADMIN			
33. 6.3	SOP-Infrastructure	ADM.SOP.01	1.0
34.	SOP Waste Management	ADM.SOP.02	1.0
35.	SOP Emergency Response	ADM.SOP.03	1.0
36.	SOP: Work Environment	ADM.SOP.04	1.0
37.	SOP-Pest Control	ADM.SOP.05	1.0
38.	SOP: Sanitation and Cleaning	ADM.SOP.06	1.0
39.	Approved Cleaning Agents List	ADM/06.LIS.01.01	1.0
PROCUREMENT & SUPPLY CHAIN			
40.	Sop-Procurement & Supply Chain	PSC.SOP.01	1.0
41.	Approved Supplier List	PSC/01.FRM.03.01	1.0
STORAGE AND WAREHOUSING			
42.	SOP Storage & Warehousing	SWH.SOP.01	1.0
43.	List of Raw Materials	-	1.0
RISK MANAGEMENT			
44.	Risk Policy	RIS.Pol.01	1.0
45.	SOP-Risk Management	RIS.SOP.01	1.0
DESIGN & DEVELOPMENT			
46.	Design & Development Policy	DD.Pol.01	1.0
47.	SOP-Design & Development	DD.SOP.01	1.0
DESIGN HISTORY FILE			

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48.	Product Realization Plan	DHF/MS.PR.01	1.0
49.	User Input	DHF/MS.UI.01	1.0
50.	Use Specification	DHF/MS.US.01	1.0
51.	Design Input Specification	DHF/MS.DI.01	1.0
52.	User Requirements	DHF/MS.DI.02	1.0
53.	Risk Management Plan	DHF/MS.RP.01	1.0
54.	Risk Management File	DHF/MS.RF.01	1.0
55.	Risk Benefit Analysis	DHF/MS.RBA.01	1.0
56.	Design execution plan	DHF/MS.DE.01	1.0
57.	Design Verification plan	DHF/MS.DVR.01	1.0
58.	Design Validation plan	DHF/MS.DVL.01	1.0
59.	Design Input Specifications	DHF/MS.DI.01	1.0
60.	Design output	DHF/MS.DO.01	2.0
61.	Design Verification	DHF/MS.DVR.02	2.0
MICROBIOLOGY			
62.	WI-Good Laboratory Practices In Micro-Lab	MBL/01.WI.01.01	1.0
63.	WI-Disinfectant Preparation, Efficacy Test & Usage	MBL/01.WI.02.01	1.0
64.	WI-Environmental Monitoring	MBL/01.WI.03.01	1.0
65.	WI-Fogging Procedure In Clean Rooms & MBL	MBL/01.WI.04.01	1.0
66.	WI- Gowning & Degowning	MBL/01.WI.05.01	1.0
67.	WI-Media Preparation & Disposal	MBL/01.WI.06.01	1.0
68.	WI-Positive And Negative Controls	MBL/01.WI.07.01	1.0
69.	WI-Sterility Test	MBL/01.WI.08.01	1.0
70.	WI-Growth Promotion Testing Of The Microbial Culture Media	MBL/01.WI.09.01	1.0
71.	WI-Microbial Limit Test	MBL/01.WI.10.01	1.0
72.	WI-Bacterial Endotoxins	MBL/01.WI.11.01	1.0

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73.	WI-Preparation Of Dilutions For Inoculation	MBL/01.WI.12.01	1.0
74.	WI-Revival, Maintenance, Subculturing And Disposal Of Microbial Cultures	MBL/01.WI.13.01	1.0
75.	WI-Validation of Aseptic Filling	MBL/01.WI.14.01	1.0
PRODUCTION			
76.	SOP-Production (Microspheres)	PRD.SOP.01	1.0
77.	WI-Process Validation	PRD/01/WI.01.01	1.0
78.	WI-Process Software Validation	PRD/01/WI.02.01	1.0
79.	WI-Primary & Secondary Emulsification	PRD/01/WI.03.01	1.0
80.	WI-Lyophilization	PRD/01/WI.04.01	1.0
81.	WI-Sieving	PRD/01/WI.05.01	1.0
82.	WI-Primary Packaging and Labeling	PRD/01/WI.06.01	1.0
83.	WI-Glassware Washing	PRD/01/WI.07.01	1.0
QUALITY CONTROL			
84.	WI-Raw Material Inspection	QC/01.WI.01.01	1.0
85.	WI-Size & Surface Morphology	QC/01.WI.02.01	1.0
86.	WI-QC Primary Packaging & Labeling	QC/01.WI.03.01	1.0
87.	WI-Drug Content	QC/01.WI.04.01	1.0
88.	WI-Finished Product Testing	QC/01.WI.05.01	1.0
REGULATORY AFFAIRS			
89.	SOP-Regulatory Affairs under PRRC	RA.SOP.01	1.0
FINANCE			
90.	SOP-Finance	FIN.SOP.01	1.0