Title of MDSAP Procedure/Policy/Guidance	MDSAP Procedure/Policy/ Guidance Number	Reviewed
MDSAP Functional Statement	MDSAP P0001	☐Yes ☐ No
MDSAP Audit Model	MDSAP P0002	☐Yes ☐ No
MDSAP Regulatory Authority Council and Lead Project Manager Authorities, Responsibilities, and Governing Rules	MDSAP P0003	☐Yes ☐ No
MDSAP Assessment Program Procedure	MDSAP AS P0005	☐Yes ☐ No
MDSAP Audit Time Calculation Procedure	MDSAP AU P0008	☐Yes ☐ No
MDSAP Regulatory Authority Council (RAC) Appointment	MDSAP P0009	☐Yes ☐ No
MDSAP AO Application for Recognition Procedure	MDSAP AS P0010	☐Yes ☐ No
MDSAP Witnessed Audit Procedure	MDSAP AS P0012	☐Yes ☐ No
MDSAP Conducting Stage 1 Assessment Procedure	MDSAP AS P0013	☐Yes ☐ No
MDSAP Special Documentary Assessment Procedure	MDSAP AS P0014	☐Yes ☐ No
MDSAP AO Nonconformities Procedure	MDSAP AS P0015	☐Yes ☐ No
On Site Assessment /Audit Procedure*(Stage 2, Surveillance, Re-cognition, Critical Locations)*	MDSAP AS P0016	☐Yes ☐ No
MDSAP Technical Reviews & Recognition Decision Making Procedure	MDSAP AS P0017	☐Yes ☐ No
MDSAP QMS Audit Report Policy	MDSAP AU P0019	☐Yes ☐ No
MDSAP Special Assessment Audit Procedure	MDSAP AS P0020	☐Yes ☐ No
Appeals Procedure	MDSAP AS P0021	☐Yes ☐ No
Implementing Suspension or Revocation of Recognition	MDSAP AS P0022	☐Yes ☐ No
Flagging/Collection and Review of AO Audit Reports	MDSAP AS P0023	☐Yes ☐ No
Type or Organization Eligible for Audit and Excluded from Participating	MDSAP AU P0024	☐Yes ☐ No

MDSAP Templates and Forms	MDSAP Document Number	Reviewed
MDSAP Project Team Work Item (PTWI) Proposal/Approval Form	MDSAP F0003.1	☐Yes ☐ No
MDSAP Assessment Program Flowchart	MDSAP AS F0005.1	☐Yes ☐ No
MDSAP AO Assessment Program Management File	MDSAP AS F0005.2	☐Yes ☐ No
MDSAP AO Assessment Program Approval Form	MDSAP AS F0005.3	☐Yes ☐ No
MDSAP Notice of Change	MDSAP AS F0005.5	☐Yes ☐ No
Auditor Training Working Instruction	MDSAP AU WI0006.1	☐Yes ☐ No
MDSAP AO Application for Recognition Form	MDSAP AS F0010.1	☐Yes ☐ No
MDSAP AO Application for Recognition Flowchart	MDSAP AS F0010.2	☐Yes ☐ No
MDSAP AO Scorecard Form	MDSAP AS F0010.3	☐Yes ☐ No
MDSAP AO Participant Agreement	MDSAP AS F0010.4	☐Yes ☐ No
AO Recognition Application Additional Information Sheet	MDSAP AS F0010.5	☐Yes ☐ No
AO Application Matrix	MDSAP AS F0010.6	☐Yes ☐ No
AO Critical Location Information Form	MDSAP AS F0010.7	☐Yes ☐ No
Auditor and Tech Expert Competency Summary	MDSAP AS F0010.8	☐Yes ☐ No
Witnessed Audit Flowchart	MDSAP AS F0012.1	☐Yes ☐ No
Witnessed Audit Manufacturer Profile Form	MDSAP AS F0012.2	☐Yes ☐ No
Witnessed Audit Report	MDSAP AS F0012.3	☐Yes ☐ No
Witnessed Audit Assessment Checklist/Performance Checks	MDSAP AS F0012.4	☐Yes ☐ No
Stage 1 Assessment Flowchart	MDSAP AS F0013.1	☐Yes ☐ No
Stage 1 Assessment Consolidated Report	MDSAP AS F0013.2	☐Yes ☐ No
Special Documentary Assessment Flowchart	MDSAP AS F0014.1	☐Yes ☐ No
Special Documentary Assessment Report Form	MDSAP AS F0014.2	☐Yes ☐ No
AO Nonconformity Flowchart	MDSAP AS F0015.1	☐Yes ☐ No
AO Nonconformity Report Form	MDSAP AS F0015.2	☐Yes ☐ No
On-Site Assessment-Audit Process Flowchart	MDSAP AS F0016.1	☐Yes ☐ No
Assessment-Audit Announcement Letter Template	MDSAP AS F0016.2	☐Yes ☐ No
Assessment Audit Plan Form	MDSAP AS F0016.3	☐Yes ☐ No
On-Site Assessment-Audit Report Form	MDSAP AS F0016.5	☐Yes ☐ No

Technical Reviews & Recognition Decision Flowchart	MDSAP AS F0017.1	☐Yes ☐ No
AO Recognition Decision Form	MDSAP AS F0017.2	☐Yes ☐ No
AO Recognition Decision Making Calculation Sheet	MDSAP AS F0017.3	☐Yes ☐ No
Letter of Recognition Template	MDSAP AS F0017.4	☐Yes ☐ No
Audit Report Letter to AOs	MDSAP AS F0017.5	☐Yes ☐ No
Audit Report Template for AO Audit Manufacturer	MDSAP AU F0019.1	☐Yes ☐ No
Special Assessment-Audit Flowchart	MDSAP AS F0020.1	☐Yes ☐ No
Special Assessment-Audit Report	MDSAP AS F0020.2	☐Yes ☐ No
Appeals Flowchart	MDSAP AS F0021.1	☐Yes ☐ No
Appeal Request and Processing Form	MDSAP AS F0021.2	☐Yes ☐ No
Implementing Suspension or Revocation of Recognition	MDSAP AS F0022.1	☐Yes ☐ No
Collection and Review of AO Audit Reports Flowchart Overview	MDSAP AU F0023.1	☐Yes ☐ No
Internal FDA Processing of AO Audit Reports Flowchart	MDSAP AU F0024.2	☐Yes ☐ No
MDSAP QMS Title of Procedure	**MDSAP QMS Procedure Number**	**Reviewed**
MDSAP QMS Quality Manual	QMS P0001	☐Yes ☐ No
MDSAP QMS Document Control and Approval Procedure	QMS P0002	☐Yes ☐ No
MDSAP QMS Quality Policy (refer to the Quality Manual - Section 5)	N/A	☐Yes ☐ No
MDSAP QMS Quality Risk Management Procedure	QMS P0004	☐Yes ☐ No
MDSAP QMS Management Responsibility and Management Review Procedure	QMS P0005	☐Yes ☐ No
MDSAP QMS Control of Nonconforming Processes or Services Procedure	QMS P0006	☐Yes ☐ No
MDSAP QMS Control of Quality Record Procedure	QMS P0007	☐Yes ☐ No
MDSAP QMS Internal Assessment Procedure	QMS P0008	☐Yes ☐ No
MDSAP QMS Corrective Action Procedure	QMS P0009	☐Yes ☐ No
MDSAP QMS Preventive Action Procedure	QMS P0010	☐Yes ☐ No
MDSAP QMS Complaints and/or Customer Feedback Procedure	QMS P0011	☐Yes ☐ No
MDSAP QMS Audit Report Processing Procedure	QMS P0012	☐Yes ☐ No

MDSAP QMS Continual Improvement Procedure	QMS P0013	☐Yes ☐ No
MDSAP QMS Training Procedure	QMS P0014	☐Yes ☐ No
MDSAP QMS Templates and Forms	**MDSAP QMS Document Number**	**Reviewed**
MDSAP QMS New Document Proposal/Change Request (NDP/CR) Form	QMS F0002.1	☐Yes ☐ No
MDSAP QMS New Document Proposal (NDP) Form	QMS F0002.2	☐Yes ☐ No
MDSAP QMS Risk Management Governance Structure	QMS F0004.1	☐Yes ☐ No
MDSAP QMS Risk Management Process Steps	QMS G0004.2	☐Yes ☐ No
MDSAP QMS Risk Management Flowchart	QMS F0004.3	☐Yes ☐ No
MDSAP QMS RM Identifying and Analyzing Risks Form	QMS F0004.4	☐Yes ☐ No
MDSAP QMS Risk Treatment Action Plan	QMS F0004.5	☐Yes ☐ No
MDSAP QMS Management Review Report Form	QMS F0005.1	☐Yes ☐ No
MDSAP QMS Management Review Agenda Form	QMS F0005.2	☐Yes ☐ No
MDSAP QMS Nonconformity Report (NCR) Form	QMS F0006.1	☐Yes ☐ No
MDSAP QMS Control of Quality Records Flowchart	QMS F0007.1	☐Yes ☐ No
MDSAP QMS Internal Assessment Summary Report Form	QMS F0008.1	☐Yes ☐ No
MDSAP QMS Internal Assessment Checklist	QMS F0008.2	☐Yes ☐ No
MDSAP QMS Internal Assessment Qualification/Training Form	QMS F0008.3	☐Yes ☐No
MDSAP QMS Internal Schedule- Instruction Form	QMS F0008.4	☐Yes ☐No
MDSAP QMS Internal Audit/Self Resolution of Findings Form	QMS F0008.5	☐Yes ☐No
MDSAP QMS Corrective Action/Problem (CAPR) Form	QMS F0009.1	☐Yes ☐No
MDSAP QMS Corrective Action/Problem (CAPR) Flowchart	QMS F0009.2	☐Yes ☐No
MDSAP QMS Complaint and Customer Feedback (CF) Form	QMS F0011.1	☐Yes ☐No
MDSAP QMS Training Review Checklist Form	QMS F0014.1	☐Yes ☐No
MDSAP QMS Training Evaluation Form	QMS F0014.2	☐Yes ☐No

International Standards	Standard Number	Reviewed
Quality Management Systems – Fundamentals and Vocabulary	ISO 9000	☐Yes ☐No
Conformity Assessment – Vocabulary and General Principles	ISO/IEC 17000	☐Yes ☐No
Medical Devices – Quality Management Systems – Requirements for regulatory purposes	ANSI/AAMI/ISO 13485	☐Yes ☐No
Quality Management Systems – Requirements	ISO 9001	☐Yes ☐No
Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies	ISO/IEC 17011	☐Yes ☐No
Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems	ISO/IEC 17021	☐Yes ☐No
Medical Devices – Application of Risk Management to Medical Devices	BS EN ISO 14971	☐Yes ☐No
Regulatory Authority Guidance Documents, Regulations and Other Materials	**Guidance Doc. No.**	**Reviewed**
AUSTRALIA		
Australian Regulatory Guidelines for Medical Devices (ARGMD)	N/A	☐Yes ☐No
Uniform Recall Procedure for Therapeutic Goods (Australia)	N/A	☐Yes ☐No
BRAZIL		
Brazilian Medical Devices Good Manufacturing Practices Resolution	RDC 16/2013	☐Yes ☐No
CANADA		
Quality Management System Audits Performed by Health Canada Recognized Registrars	GD210: ISO 13485	☐Yes ☐No
JAPAN		
Japanese QMS Ordinance	MHLW MO169	☐Yes ☐No
UNITED STATES		
Guidance Document - Medical Device Reporting for Manufacturers	N/A	☐Yes ☐No
Compliance Program Guidance Manual – Inspection of Medical Device Manufacturers	7382.845	☐Yes ☐No
Guidance Document – Design Control Guidance for Medical Device Manufacturers	N/A	☐Yes ☐No
Investigations Operations Manual (IOM)	N/A	☐Yes ☐No

(OPTIONAL)		
Regulatory Procedures Manual (RPM)	N/A	☐Yes ☐No
Guide To Inspections of Quality Systems – QSIT *(OPTIONAL)*	N/A	☐Yes ☐No
IMDRF DOCUMENTS		
Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition	IMDRF/MDSAP/ WG/N3	☐Yes ☐No
Competence and Training Requirements for Auditing Organizations	IMDRF/MDSAP/ WG/N4	☐Yes ☐No
Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations	IMDRF/MDSAP/ WG/N5	☐Yes ☐No
Regulatory Authority Assessor Competence and Training Requirements	IMDRF/MDSAP/ WG/N6	☐Yes ☐No
Grading Nonconformities Issued to Auditing Organizations by Recognizing Regulatory Authorities; and Decision-Making Principles and Criteria for the Recognition of Auditing Organization	IMDRF/MDSAP/ WG/N11	☐Yes ☐No