1. **General Information**

|  |  |
| --- | --- |
| Auditing Organization (AO)  (Name and Head-Office Address) |  |
| AO ID# |  |
| Contact person | Name:  Title:  Tel.:  Fax.:  E-mail: |
| Objectives | * Evaluate the adequacy of the AO's auditing practices against requirements of ISO/IEC 17021-1:2015, specific MDSAP auditing requirements, and AO policies and procedures * Evaluate the AO's ability to evaluate and assign auditors based on demonstrated competence (e.g. knowledge and understanding of the MDSAP audit process, QMS and other regulatory requirements, and the technologies audited) * Evaluate the AO’s ability to generate reliable audit reports, including nonconformity reports, enabling the users of these data to make informed decisions |
| Scope of the audit | Assessment of:   * The planning activities prior to the audit (e.g. the audit Program, the audit plan, the assignment of the audit team, communication prior to the audit) * The preparedness of the audit team * The audit technique employed against MDSAP audit process requirements * The competence of the audit team * The deliverables of the audit (e.g. audit report, nonconformity reports, etc.) |
| AO Scope of Recognition | See Attachment #1 |
| Assessment criteria | * ISO/IEC 17021-1:2015 – Conformity assessment – Requirements for bodies providing audit and certification of management systems * IMDRF MDSAP WG/N3(ed2) – Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition * IMDRF MDSAP WG/N4 – Competence and Training Requirements for Auditing Organizations |
| Reference documents | * IMDRF MDSAP WG/N5: Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations * MDSAP Audit Model * GHTF/SG3/N19:2012 – Nonconformity grading system for regulatory purpose and information exchange * MDSAP AU P0008 – Audit Time Calculation Procedure * MDSAP AU P0019 – MDSAP Regulatory Audit Report Policy * Australian Medical Device Regulations * Brazilian Medical Device Good Manufacturing Practices (Resolution RDC 16/2013) * Brazilian Post-Market Surveillance and Medical Device Reporting (Resolution RDC 67/2009) * Brazilian Field Actions (Resolution RDC 23/2012) * Canadian Medical Device Regulations (applicable parts of SOR-98/282) * Japanese Medical Device Regulations (PMD Act) * Japanese QMS Ordinance (MHLW MO169) * US Medical Device Regulations (21 CFR parts 820, 803, 806, 807, 814 and 821) |
| On-site audit date(s) | YYYY-MM-DD |

1. **Assessment Summary**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The outcome of the audit shows:   |  |  | | --- | --- | | **🞏** | {Number of} Nonconformities | | **🞏** | {Number of.} Observation | | **🞏** | {Number of} Points to Clarify | | **🞏** | None of the above. | |

1. **Assessment Findings**

|  |  |
| --- | --- |
| **Non-Conformities** {🡪 complete corresponding non-conformity forms MDSAP F0015.2} | |
| 1 |  |
| 2 |  |
| 3 |  |
| **Observations** | |
| 1 |  |
| 2 |  |
| 3 |  |
| **Points to Clarify** | |
| 1 |  |
| 2 |  |
| 3 |  |

*{This section details all findings. Delete any category that is not applicable from the following table. Add rows as needed. If “None of the above” in Section 3 is checked, please provide “Not Applicable” only in this section.}*

1. **Conclusion**

|  |  |
| --- | --- |
| Conclusion regarding  - performance of the audit  and certification decision  process  - conformity to the  assessment criteria  - confidence in the ability of  the AO to reliably audit  and certify the compliance  of device manufacturers to  ISO 13485:2016 and their  ability to satisfy regulatory  requirements |  |

1. **Audited Organization**

|  |  |
| --- | --- |
| Manufacturer’s name |  |
| Address(es) |  |
| Scope of certification |  |
| AO location involved in the audit and certification process for this manufacturer |  |
| Comments |  |

1. **Assessment Findings**

|  |  |  |  |
| --- | --- | --- | --- |
| **Audit Planning and Audit Team Preparedness** | | | |
| Documents provided prior to the audit | AO's manuals, procedures, guidelines relative to the certification process and performance of audits | Yes | No |
| AO's descriptive information on the device manufacturer |  |  |
| Audit Program for the current certification cycle and prior audit reports (from on-going cycle or previous cycle in case of recertification audit). |  |  |
| Audit team information (contact info + competence) |  |  |
| Rationale for the selection of the audit team |  |  |
| Rationale for the audit duration |  |  |
| Information provided to the audit team |  |  |
| Device manufacturer documentation (quality manual and other documents provided for the preparation of the audit |  |  |
| Prior assessment report(s):   * If initial audit: outcome of Stage 1 * If re-audit: all audit reports from the cycle |  |  |
| Audit plan established by the audit team |  |  |
| Comments |  | | |
| Conclusion |  | | |

|  |  |
| --- | --- |
| **Audit team Competence and Behaviour** | |
| Comments on knowledge of the technical area |  |
| Comments on knowledge of ISO 13485:2016 and Good Manufacturing Practices |  |
| Comments on knowledge of other medical device regulatory requirements |  |
| Comments on auditing skills (except MDSAP Audit Model) |  |
| Comments on behaviour |  |
| Comments on opening meeting and closing meeting |  |
| Conclusion |  |

|  |  |
| --- | --- |
| **MDSAP Auditing Approach** | |
| Comments on the audit of Management |  |
| Comments on the audit of the Device Marketing Authorization and Facility Registration |  |
| Comments on the audit of Measurement, Analysis and Improvement |  |
| Comments on the audit of Design and Development |  |
| Comments on the audit of Medical Device Adverse Events and Advisory Notice Reporting |  |
| Comments on the audit of Production and Process Control |  |
| Comments on the audit of Purchasing |  |
| Conclusion |  |

|  |  |
| --- | --- |
| **Nonconformities and Final Report** | |
| Comments on the audit thoroughness and the audit team’s ability to identify nonconformities |  |
| Comments on the nonconformity reports, including their grading and the evidence supporting them |  |
| Comments on the communication of the nonconformities to the manufacturer |  |
| Comments on the compliance of the audit report to the MDSAP Audit Report Procedure and Template on the content of regulatory audit reports |  |
| Comments on the consistency between the audit performed and the audit report |  |
| Comments on fulfilment of audit objectives, specific to the audit type and the audit program |  |
| Conclusion |  |

1. **List of Attachments**

|  |  |
| --- | --- |
| 1 | Scope of recognition (Extract from Assessment Program Management File) |
| 2 |  |
| 3 |  |

1. **List of Exhibits**

|  |  |
| --- | --- |
| 1 |  |
| 2 |  |
| 3 |  |

1. **Assessment Team**

|  |  |
| --- | --- |
| Assessor Name |  |
| MDSAP Participating Regulatory Authority |  |
| Assessor’s Role | {Assessment team leader, Assessor, Technical expert} |
| Date | YYYY/MM/DD |
| Signature |  |

*{Add as many Assessors as applicable}*

1. **List of Attachments**

|  |  |
| --- | --- |
| 1 | Scope of recognition |
| 2 | Comprehensive MDSAP auditing model checklist, with scoring system |
| 3 |  |

1. **List of Exhibits**

|  |  |
| --- | --- |
| 1 | AO audit report |
| 2 |  |
| 3 |  |