1. **General Information**

|  |  |
| --- | --- |
| Auditing Organization (AO) | (Name and Head-Office Address) |
| AO ID# |  |
| Contact person | Name:Title:Tel.:Fax.: E-mail: |
| Objectives |  |
| Scope of the assessment | Facility (See addresses in Attachment #1 – Assessment Plan) | Processes |
| Management | Use of External Resources | Measurement, Analysis & Improvement | Competence Management | Audit & Certification Decision  | Information Management  |
| [ ]  Head Office | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| [ ]  Critical Location # | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Assessment criteria | * ISO/IEC 17021-1:2015 – Conformity assessment – Requirements for bodies providing audit and certification of management systems
* IMDRF/MDSAP WG/N3 (2nd Edition) – Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
* IMDRF/MDSAP WG/N4　(2nd Edition) – Competence and Training Requirements for Auditing Organizations
 |
| Reference documents | * MDSAP AS P0034 - Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations
* MDSAP AU P0002 - MDSAP Audit Approach
* 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 665/2022)
* Brazilian Post-Market Surveillance and Medical Device Reporting (Resolution RDC 67/2009)
* Brazilian Field Actions (Resolution RDC 551/2021)
* 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 assessment shows:

|  |  |
| --- | --- |
| **🞏** | {No.} Non-conformities  |
| **🞏** | {No.} Observation |
| **🞏** | {No.} Points to Clarify  |
| **🞏** | None of the above.  |

 |

1. **Assessment Findings**

|  |
| --- |
| **Non-Conformities {🡪 complete corresponding non-conformity forms [ref.]}** |
| 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.}*

|  |
| --- |
| **Status of nonconformities from previous assessment activities**  |
| NC Ref. | Status (see details in the NC report) |
|  |  |
|  |  |
|  |  |

See details of the assessment findings in the Attachment #3 of this report

1. **Conclusion**

|  |  |
| --- | --- |
| * Conclusion regarding establishment and implementation of the AO’s QMS
* Conformity to the assessment criteria
* Confidence in the ability of the AO to reliably audit and certify the compliance of MD manufacturers to ISO 13485 and their ability to satisfy regulatory requirements
 |  |

1. **List of Attachments**

|  |  |
| --- | --- |
| 1 |  |
| 2 | Review of a sample of AO Audit Reports prior to the on-site visit (if applicable). |
| 3 | Narrative of the On-Site Assessment |

1. **List of Exhibits**

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

1. **Assessor(s)**

|  |  |
| --- | --- |
| Assessor Name |  |
| Regulatory Authority |  |
| Assessor’s Role | {assessment team leader, assessor} |
| Date |  |
| Signature |  |

*{Add as many Assessors as applicable}*

**Attachment 2: Review of a sample of AO Audit Reports prior to the on-site visit (if applicable).**

|  |  |
| --- | --- |
| Auditing Organization (AO) |  |
| AO ID# |  |
| Report # |  |
| Objectives | Review of a representative sample of audit reports shared by the AO with RA, for conformity with applicable audit report requirements |
| Assessment criteria | IMDRF/MDSAP WG/N3 (2nd Edition)MDSAP Audit ModelMDSAP AU P0019 - MDSAP Medical Device Audit Report Policy |

1. **Sampling**

|  |  |
| --- | --- |
| Time period considered | From: YYYY-MM-DDTo: YYYY-MM-DD |
| Number of audit reports during this period by the AO |  |
| Sampling | Size (number):  | 🞏 Audit reports 🞏 Audit files |

1. **List of audit reports/files reviewed**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **#** | **Report Ref.** | **Medical Device Manufacturer** | **Audit dates** | **Audit type** | **Auditor(s)** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **4** |  |  |  |  |  |
| **5** |  |  |  |  |  |
| **6** |  |  |  |  |  |
| **7** |  |  |  |  |  |
| **8** |  |  |  |  |  |
| **9** |  |  |  |  |  |
| **10** |  |  |  |  |  |

*{Remove or add rows as necessary}*

1. **Findings of the Audit Report Sample Review**

| **Review Criteria:****The report:** | **Report[[1]](#footnote-1)** |
| --- | --- |
| **#1** | **#2** | **#3** | **#4** | **#5** | **#6** | **#7** | **#8** | **#9** | **#10** |
| Is uniquely identified |  |  |  |  |  |  |  |  |  |  |
| Is typed and electronically text-searchable |  |  |  |  |  |  |  |  |  |  |
| Is written in English, French or Portuguese[[2]](#footnote-2) |  |  |  |  |  |  |  |  |  |  |
| Identifies its author(s) |  |  |  |  |  |  |  |  |  |  |
| Is dated |  |  |  |  |  |  |  |  |  |  |
| Includes the following information on manufacturer: |
| Name and address of the manufacturer, and it matches the information provided by the manufacturer for registration |  |  |  |  |  |  |  |  |  |  |
| Identification number (Canada, US), and it matches the ID # generated by the Regulatory Authorities |  |  |  |  |  |  |  |  |  |  |
| Indication on whether other names are used by the manufacturer |  |  |  |  |  |  |  |  |  |  |
| Relationship with other entities of the corporation (parent, sister and daughter companies, including subsidiaries, acquisitions, business units, and joint Ventures) [[3]](#footnote-3) |  |  |  |  |  |  |  |  |  |  |
| Description of the manufacturer (including # of employees, # of shifts, overview of activities and processes carried out at the audited location(s), identification of key outsourced activities, name and title of senior management of the location(s) audited) |  |  |  |  |  |  |  |  |  |  |
| Scope of certification (including activities and list of product groups or families) |  |  |  |  |  |  |  |  |  |  |
| Critical suppliers (including name, address, and product or service of criticalsuppliers that provide products or services used in the audited processes) |  |  |  |  |  |  |  |  |  |  |
| Contact person for the QMS |  |  |  |  |  |  |  |  |  |  |
| Status of any relevant QMS certification |  |  |  |  |  |  |  |  |  |  |
| List of ISO 13485 requirements excluded or deemed non applicable |  |  |  |  |  |  |  |  |  |  |
| Includes the following information about the audit |
| Audit type |  |  |  |  |  |  |  |  |  |  |
| Audit criteria |  |  |  |  |  |  |  |  |  |  |
| Audit objectives |  |  |  |  |  |  |  |  |  |  |
| Audit scope |  |  |  |  |  |  |  |  |  |  |
| Audit dates |  |  |  |  |  |  |  |  |  |  |
| Audit team identification |  |  |  |  |  |  |  |  |  |  |
| Audit language |  |  |  |  |  |  |  |  |  |  |
| Document review results |  |  |  |  |  |  |  |  |  |  |
| Includes the following information about the audit findings |
| Sufficient audit findings, both positive and negative, to support the audit conclusions made in the report |  |  |  |  |  |  |  |  |  |  |
| No advice, instructions or solutions, nor opportunities for improvement |  |  |  |  |  |  |  |  |  |  |
| Audit summaries, for each audited process (per MDSAP), including the following: |  |  |  |  |  |  |  |  |  |  |
| * *Description of the QMS process or activity audited*
 |  |  |  |  |  |  |  |  |  |  |
| * *Area (physical or organizational) of the site visited*
 |  |  |  |  |  |  |  |  |  |  |
| * *Name and title of persons interviewed*
 |  |  |  |  |  |  |  |  |  |  |
| * *Key documents reviewed (procedures, work instructions, etc.)*
 |  |  |  |  |  |  |  |  |  |  |
| * *Type and number of records reviewed, including a qualitative statement of the sample size where appropriate*
 |  |  |  |  |  |  |  |  |  |  |
| * *Identification of products or components reviewed*
 |  |  |  |  |  |  |  |  |  |  |
| * *Statements regarding the conformity of the activity or process under audit to the audit criteria*
 |  |  |  |  |  |  |  |  |  |  |
| Description of Major Changes |  |  |  |  |  |  |  |  |  |  |
| Obstacles |  |  |  |  |  |  |  |  |  |  |
| Follow-up on past nonconformities |  |  |  |  |  |  |  |  |  |  |
| Nonconformities, including |  |  |  |  |  |  |  |  |  |  |
| * *Statement of nonconformity*
 |  |  |  |  |  |  |  |  |  |  |
| * *Criterion not met*
 |  |  |  |  |  |  |  |  |  |  |
| * *Supporting evidence*
 |  |  |  |  |  |  |  |  |  |  |
| * *Grading*
 |  |  |  |  |  |  |  |  |  |  |
| Areas not audited (although part of the audit scope and plan) |  |  |  |  |  |  |  |  |  |  |
| Includes the following information as part of the conclusions |
| Conformity with audit criteria |  |  |  |  |  |  |  |  |  |  |
| Effectiveness |  |  |  |  |  |  |  |  |  |  |
| Confirmation of audit objectives |  |  |  |  |  |  |  |  |  |  |
| Reliability of audit |  |  |  |  |  |  |  |  |  |  |
| Recommendations |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **Reviewer General Conclusion** | **The audit report:** |  |  |  |  |  |  |  |  |  |  |
| **Is relevant** (the information is meaningful and addresses the objectives of the audit) |  |  |  |  |  |  |  |  |  |  |
| **Is consistent** (no ambiguous or contradictory information with regards to the conformity with ISO 13485:2016 or the achievement of the audit objectives) |  |  |  |  |  |  |  |  |  |  |
| **Is credible** (the review of the report does not question the competence of the auditor) |  |  |  |  |  |  |  |  |  |  |
| **Is reliable** (the conclusions are substantiated and can be trusted) |  |  |  |  |  |  |  |  |  |  |
| **Is acceptable** (it demonstrates the proper implementation of the MDSAP program as applicable to the audit report) |  |  |  |  |  |  |  |  |  |  |

1. **List of comments**

|  |  |
| --- | --- |
| **#** | **Comments** |
| **1** |  |
| **2** |  |
| **3** |  |
| **4** |  |
| **5** |  |
| **6** |  |
| **7** |  |
| **8** |  |
| **9** |  |
| **10** |  |
| **11** |  |
| **12** |  |
| **13** |  |
| **14** |  |
| **15** |  |
| **16** |  |
| **17** |  |
| **18** |  |
| **19** |  |
| **20** |  |

*{Add or remove lines as necessary}*

*Note: These comments are identified prior to the on-site assessment as an input for this activity. When assessors determine at the end of the On-Site Assessment that a comment is not a nonconformity, a rationale should be added (it may be a reference to a paragraph in the body of the report)*

**Attachment 3: Narrative**

|  |
| --- |
| **Major Changes** |
| Major changes to :* Processes
* Organizational structure or ownership,
* Key personnel
* Facilities
* QMS as a whole
* and their relevance and impact on compliance to the IMDRF recognition Criteria
 |  |

Findings by assessment process

|  |
| --- |
| **Management**  |
| Individuals interviewed |  |
| Main documents / information reviewed |  |
| Description / finding |  |
| Conclusion |  |

|  |
| --- |
| **Use of External Resources**  |
| Individuals interviewed |  |
| Main documents / information reviewed |  |
| Description / finding |  |
| Conclusion |  |

|  |
| --- |
| **Measurement, Analysis & Improvement**  |
| Individuals interviewed |  |
| Main documents / information reviewed |  |
| Description / finding |  |
| Conclusion |  |

|  |
| --- |
| **Competence Management**  |
| Individuals interviewed |  |
| Main documents / information reviewed |  |
| Description / finding |  |
| Conclusion |  |

|  |
| --- |
| **Audit & Certification Decision**  |
| Individuals interviewed |  |
| Main documents / information reviewed |  |
| Description / finding |  |
| Conclusion |  |

|  |
| --- |
| **Information Management**  |
| Individuals interviewed |  |
| Main documents / information reviewed |  |
| Description / finding |  |
| Conclusion |  |

1. Specify, for each report, the reference number of the comments.
Note: the same comment may apply to several reports. Several comments may apply to the same report with regards to a single criterion listed above. [↑](#footnote-ref-1)
2. If to be used by Health Canada, a version of the report must be available in either English or French [↑](#footnote-ref-2)
3. This may be omitted in surveillance audit reports [↑](#footnote-ref-3)