1. **General Information**

|  |  |
| --- | --- |
| Auditing Organization (AO) |  |
| AO ID# |  |
| Contact person | Name:Title:Tel.Fax. E-mail |
| Special Remote Assessment objectives |  |
| Review criteria | - ISO/IEC 1702-1:2015 – Conformity assessment – Requirements for bodies providing audit and certification of management systems- IMDRF/MDSAP WG/N3:2016 (2nd Edition) – Recognition of organizations undertaking audits of medical device manufacturers 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 65/2022)- 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) |
| Assessment date(s) | YYYY-MM-DD |

1. **Assessment Finding Summary**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The outcome of the special documentary assessment shows:

|  |  |
| --- | --- |
| **🞏** | {Number.} Non-conformities  |
| **🞏** | {Number.} Observation |
| **🞏** | {Number.} Issues requiring clarification  |
| **🞏** | None of the above.  |

 |

1. **Assessment Findings**

|  |
| --- |
| **Non-Conformities (NC) {🡪 complete corresponding non-conformity forms [ref.]}** |
| 1 |  |
| 2 |  |
| 3 |  |
| **Observations** |
| 1 |  |
| 2 |  |
| 3 |  |
| **Issues requiring clarification** |
| 1 |  |
| 2 |  |
| 3 |  |

*{This section details all findings, including NC, observations, and issues requiring clarifications. Delete any category in this table that is not applicable. Add rows as needed. If “None of the above” in Section 3 is checked, please indicate “Not Applicable” only in this section.}*

1. **Conclusion of the assessors**

|  |  |
| --- | --- |
| Fulfilment of the assessment objectives |  |
| Compliance of the AO to the assessment criteria |  |

1. **Assessors**

|  |  |
| --- | --- |
| Assessor Name |  |
| Regulatory Authority |  |
| Assessor’s Role | Assessment Team Leader |
| Date |  |
| Signature |  |

|  |  |
| --- | --- |
| Assessor Name |  |
| Regulatory Authority |  |
| Assessor’s Role | {Assessor, Observer} |
| Date |  |
| Signature |  |

*{Add as many Assessors as applicable}*

1. **Appendices**

Appendix 1: Narrative of the Special Remote Assessment

**Appendix 1:** Narrative of the Special Remote Assessment

|  |
| --- |
|  |

*{Document in particular}*

1. *The reference of the assessed documents,*
2. *The reference of impacted documents (like AO nonconformity reports),*
3. *The analysis of these documents with regard to the special documentary assessment objectives and the compliance to the assessment criteria,*
4. *The status of the assessment objectives (satisfied, pending additional evidence),*
5. *Whether a teleconference took place and who the interlocutors were.*