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| Section 1. Audit Information | | | | | | |
| **Auditing Organization** | |  | | | | |
| **Audit Starting Date** |  | | **Audit Ending Date** |  | **Duration of Audit [[1]](#endnote-1)** |  |
| **AO Audit Report Ref [[2]](#endnote-2)** |  | | | **Languages** |  | |
| **Auditors (Initials) [[3]](#endnote-3)** |  | | | | | |

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| Section 2. Audited Facility | | | | | | | | |
| **Name & Address** | |  | | | **MDSAP Facility Identifier [[4]](#endnote-4)** | |  | |
| **Contact Person [[5]](#endnote-5)** (Title, Email, Telephone) | |  | | | | | | |
| **Senior Management at Audited Facility** | |  | | | | | | |
| **Australia-TGA** | **Brazil – ANVISA** | | **Canada – Health Canada** | **Japan – MHLW/PMDA** | | **USA - FDA** | | **Other** |
|  |  | |  |  | |  | |  |

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| Section 3. Certification Schemes, Scopes &Criteria, Audit type | | | |
| **Audit Type** |  | | |
| **Scope of Certification [[6]](#endnote-6)** | | |  |
| **Country-specifics [[7]](#endnote-7)** | |  | |
| Note: CE Marking Cert. Scheme is always **Not Applicable** | | | |

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| Section 4. Certification Holder and Multi-site Organization | |
| **Corporate Information [[8]](#endnote-8)** |  |

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| Section 5. Audit Objectives |
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| NOTE: This is a fixed statement depending on the type of Audit. May be clear in Audit Plan, also see Doc.#MDSAP AU P0019.004 (2.3.2) |

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| Section 6. Audited Facility Description | | |
| **Regulatory Roles played by the Audited Facility, considered in the scope of the audit [[9]](#endnote-9)** | |  |
| **Activities at the Audited Facility [[10]](#endnote-10)** |  | |
| Note: For “Regulatory Roles”: [**Australia]** Either “Manufacturer” or “Supplier” Supplier cannot have a MDSAP certificate because supplier is NOT a legal manufacturer. [**Canada**] Only “Manufacturer”. [**Japan**] “Registered Manufacturing Site (RMS)” or “Marketing Authorization Holder (MAH)”. Not clear how to know which. This information should be added to QQ - Appendix MDSAP. [**USA**] Visit the [FDA site LINK](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm). Type in the applicant name in the column “Owner/Operator Name” and press Search. Find the name you’ve typed in in “Establishment Name” and you will find the information in the column “Current Registration Yr” | | |

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| Section 7. Critical Suppliers (to include outsourced processes) [[11]](#endnote-11) | | | |
| **Supplier 1 Name / Address** |  | **Products / Services used** |  |
| **Supplier 2 Name / Address** |  | **Products / Services used** |  |
| **Supplier 3 Name / Address** |  | **Products / Services used** |  |
| **Supplier 4 Name / Address** |  | **Products / Services used** |  |

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| Section 8. Audit History (All Audit / Certification Scheme Considered) [[12]](#endnote-12) | | | | | | |
| **Date** |  | | **Report Ref** |  | **Audit Type** |  |
| **Summary of Findings** | |  | | | | |

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| Section 9. Exclusions and Non-Applications of Requirements in the QMS [[13]](#endnote-13) |
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| Section 10. Outcome of Pre-Audit Activities (including Stage 1 as applicable) [[14]](#endnote-14) |
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| Section 11. Audit Findings [[15]](#endnote-15) |
| Section 11.1 – Process: Management |
| **Description of the audited process or activity, and area (physical or organizational)** |
| **TASK 1 – Quality Management System Planning [AUDITOR NAME]**  **TASK 2 – Management Representative [XXX]**  **TASK 3 – Quality Policy and Quality Objectives [XXX]**  **TASK 4 – Organizational Structure, Responsibility, Authority, Resources [XXX]**  **TASK 5 – Extent of Outsourcing [XXX]**  **{TGA}**  **{HC}**  **TASK 6 – Personnel Competency & Training [XXX]**  **{ANVISA}**  **TASK 7 – Risk Management Planning and Review [XXX]**  **TASK 8 – Document Controls [XXX]**  **{TGA}**  **{ANVISA}**  **{MHLW}**  **{FDA}**  **TASK 9 – Management Reviews [XXX]**  **TASK 10 – Distribution of Devices with Appropriate Marketing Authorization [XXX]**  **TASK 11 – Top Management Commitment to Quality [XXX]** |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
|  |
| **Concluding statement regarding whether the audited activities processes are in conformity with the audit criteria [[16]](#endnote-16) [**[**LINK**](http://ibb.hu/task.php?t=)**]** |
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| Section 11.2 – Process: Device Marketing Authorization and Facility Registration |
| **Description of the audited process or activity, and area (physical or organizational)** |
| **TASK 1 – Submission for Device Marketing Authorization and Facility Registration [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}**  **TASK 2 – Evidence of Marketing Clearance or Approval [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}**  **TASK 3 – Notification of Changes to Marketed Devices or to the QMS [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}** |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
|  |
| **Concluding statement regarding whether the audited activities processes are in conformity with the audit criteria [**[**LINK**](http://ibb.hu/task.php?t=)**]** |
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| Section 11.3 – Process: Measurement, Analysis and Improvement |
| **Description of the audited process or activity, and area (physical or organizational)** |
| **TASK 1 – Procedures for Measurement, Analysis, & Improvement of QMS Effectiveness and Product Conformity [XXX]**  **{ANVISA}**  **{FDA}**  **TASK 2 – Sources of Quality Data [XXX]**  **TASK 3 – Investigation of Nonconformity [XXX]**  **TASK 4 – Investigation of Potential Nonconformity [XXX]**  **TASK 5 – Correction, Corrective Action, and Preventive Action [XXX]**  **TASK 6 – Assessment of Design Change resulting from Corrective or Preventive Action [XXX]**  **TASK 7 – Assessment of Process Change resulting from Corrective or Preventive Action [XXX]**  **{TGA}**  **{HC}**  **{MHLW}**  **TASK 8 – Identification and Control of Nonconforming Product [XXX]**  **TASK 9 – Action Regarding Nonconforming Product Detected After Delivery [XXX]**  **TASK 10 – Internal Audit [XXX]**  **TASK 11 – Information Supplied for Management Review [XXX]**  **TASK 12 – Evaluation of Information from Post-Production Phase, Including Complaints [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}**  **TASK 13 – Communications with External Parties Involved on Complaints [XXX]**  **TASK 14 – Notification of Adverse Events [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}**  **TASK 15 – Notification of Advisory Notices [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}**  **TASK 16 – Top Management Commitment to Measurement, Analysis, and Improvement Process [XXX]** |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
|  |
| **Concluding statement regarding whether the audited activities processes are in conformity with the audit criteria [**[**LINK**](http://ibb.hu/task.php?t=)**]** |
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| Section 11.4 – Process: Medical Device Adverse Events and Advisory Notice Reporting |
| **Description of the audited process or activity, and area (physical or organizational)** |
| **TASK 1 – Notification of Adverse Events [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}**  **TASK 2 – Notification of Advisory Notices [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}** |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
|  |
| **Concluding statement regarding whether the audited activities processes are in conformity with the audit criteria [**[**LINK**](http://ibb.hu/task.php?t=)**]** |
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| Section 11.5 – Process: Design and development |
| **Description of the audited process or activity, and area (physical or organizational)** |
| **TASK 1 – Identification of Devices Subject to Design and Development Procedure; Technical Documentation [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **TASK 2 – Selection of a Completed Design and Development Project [XXX]**  **TASK 3 – Design and Development Planning [XXX]**  **{TGA}**  **{HC}**  **TASK 4 – Implementation of the Design and Development Process [XXX]**  **{FDA}**  **TASK 5 – Design and Development Input [XXX]**  **{TGA}**  **{FDA}**  **TASK 6 – Completeness, Coherence, and Unambiguity of Design and Development Input [XXX]**  **TASK 7 – Design and Development Output and Design Verification [XXX]**  **{TGA}**  **TASK 8 – Risk Management Activities Applied throughout the Design and Development Project [XXX]**  **{ANVISA}**  **{FDA}**  **TASK 9 – Design Verification or Design Validation to Confirm Effectiveness of Risk Control Measures [XXX]**  **TASK 10 – Design Validation [XXX]**  **TASK 11 – Clinical Evaluation and/or Evaluation of Medical Device Safety and Performance [XXX]**  **{TGA}**  **TASK 12 – Software Specifics [XXX]**  **TASK 13 – Design and Development Change [XXX]**  **{TGA}**  **{ANVISA}**  **{HC}**  **{MHLW}**  **{FDA}**  **TASK 14 – Design Review [XXX]**  **{FDA}**  **TASK 15 – Impact Review of Design and Development Changes on Previously Made and Distributed Devices [XXX]**  **TASK 16 – Design Transfer [XXX]**  **{ANVISA}**  **TASK 17 – Top Management Commitment to Design and Development Process [XXX]** |
| **Selected design file and rationale for the selection** |
|  |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
|  |
| **Concluding statement regarding whether the audited activities processes are in conformity with the audit criteria [**[**LINK**](http://ibb.hu/task.php?t=)**]** |
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| Section 11.6 – Process: Production and Service control |
| **Description of the audited process or activity, and area (physical or organizational)** |
| **TASK 1 – Planning of Production and Service Process [XXX]**  **{FDA}**  **TASK 2 – Selection of Production and Service Process(es) [XXX]**  **TASK 3 – Controls for the Implementation of Selected Production and Service Process(es) [XXX]**  **TASK 4 – Control of Product Cleanliness [XXX]**  **{ANVISA}**  **TASK 5 – Infrastructure [XXX]**  **{ANVISA}**  **TASK 6 – Work Environment [XXX]**  **{ANVISA}**  **TASK 7 – Identification of Processes Subject to Validation [XXX]**  **{ANVISA}**  **{FDA}**  **TASK 8 – Process Validation [XXX]**  **{TGA}**  **TASK 9 – Validation of Sterilization Process [XXX]**  **{TGA}**  **TASK 10 – Monitoring and Measurement of Product Conformity [XXX]**  **TASK 11 – Control, Operation, and Monitoring of the Production and Service Process; Risk Controls [XXX]**  **TASK 12 – Competence of Personnel [XXX]**  **TASK 13 – Control of Monitoring and Measuring Device [XXX]**  **TASK 14 – Impact Analysis of Monitoring and Measuring Device Found Out of Specifications [XXX]**  **TASK 15 – Validation of Software Used for the Control of the Production and Service Process [XXX]**  **TASK 16 – "Device Master File" [XXX]**    **{ANVISA}**  **{HC}**  **{FDA}**  **TASK 17 – Production Record; Evidence of Compliance of Released Devices [XXX]**    **{ANVISA}**  **{FDA}**  **TASK 18 – Traceability Applied to Implantable, Life-Supporting or Life-Sustaining Medical Devices [XXX]**  **{HC}**  **{FDA}**  **TASK 19 – Identification of Product Status [XXX]**  **TASK 20 – Customer Property [XXX]**  **TASK 21 – Acceptance Activities [XXX]**  **{ANVISA}**  **{FDA}**  **TASK 22 – Identification, Control, and Disposition of Nonconforming Products [XXX]**  **TASK 23 – Rework of Nonconforming Products [XXX]**  **TASK 24 – Preservation of the Product [XXX]**  **TASK 25 – Review of Customer Requirements, Distribution Records [XXX]**  **{ANVISA}**  **{HC}**  **{FDA}**  **TASK 26 – Installation Activities [XXX]**  **TASK 27 – Servicing Activities [XXX]**  **{ANVISA}**  **{FDA}**  **TASK 28 – Risk Controls Applied to Transport, Installation, and Servicing [XXX]**  **TASK 29 – Top Management Commitment to the Production and Service Process [XXX]** |
| **Selected Production and Service and rationale for the selection** |
|  |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
|  |
| **Concluding statement regarding whether the audited activities processes are in conformity with the audit criteria [**[**LINK**](http://ibb.hu/task.php?t=)**]** |
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| Section 11.7 – Process: Purchasing |
| **Description of the audited process or activity, and area (physical or organizational)** |
| **TASK 1 – Planning Activities Regarding Purchased Products and Outsourced Processes [XXX]**  **TASK 2 – Selection of Supplier File to Audit [XXX]**  **TASK 3 – Procedure for the Control of Purchased Products and Outsourced Processes [XXX]**  **TASK 4 – Extent of Controls Applied to the Supplier and the Purchased Product; Criteria for Selection, Evaluation, and Re-evaluation of the Supplier [XXX]**  **TASK 5 – Selection of Supplier Based on Ability of the Supplier to Satisfy the Specified Purchase Requirements [XXX]**  **{TGA}**  **{HC}**  **{MHLW}**  **TASK 6 – Records of Supplier Evaluation [XXX]**  **TASK 7 – Effective Controls over Supplier and Products [XXX]**  **TASK 8 – Verification of the Adequacy of Purchasing Information, Specified Purchase Requirements,**  **and Written Agreement to Notify Changes, before their Communication to the Supplier [XXX]**  **{ANVISA}**  **TASK 9 – Documented Purchasing Information and Specified Purchase Requirements [XXX]**  **TASK 10 – Verification of Purchased Products [XXX]**  **{ANVISA}**  **TASK 11 – Purchasing Control Activities as Source of Quality Data for the Measurement, Analysis, and Improvement Process [XXX]**  **TASK 12 – Top Management Commitment to the Purchasing Process [XXX]** |
| **Selected Supplier File and rationale for the selection** |
|  |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
|  |
| **Concluding statement regarding whether the audited activities processes are in conformity with the audit criteria [**[**LINK**](http://ibb.hu/task.php?t=)**]** |
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| Section 11.8 – Other Findings |
| **Findings relative to requirements specific to certification schemes other than MDSAP** |
|  |
| **Key documents reviewed related to this specific process or TASK** |
|  |
| **Name and Titles of persons interviewed** |
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| Section 12. Nonconformities [[17]](#endnote-17) |
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| Section 13. Significant Deviation from the Audit Plan [[18]](#endnote-18) |
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| Section 14. Follow-up of Past Nonconformities |
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| Section 15. Summary of Major Changes to Audited Facility |
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| Section 16. Conclusions |
| **Conformity with Audit Criteria** |
|  |
| **Effectiveness of the QMS in meeting Quality Objective** |
|  |
| **Achievement of Audit Objective** |
|  |
| **Factors encountered that may affect the Audit Reliability** |
|  |
| **Recommendation on the Certification Status** |
|  |
| **Recommendations on -Audit Program, Audit Team, Competence, -Audit Duration** |
|  |

**Endnotes**

1. Find from either (1) Approved “**Man-day Calculation Record”** or (2) “**Audit Plan”** [↑](#endnote-ref-1)
2. Find in “**Report Number Table”** located on H-Drive. Confirm with Coordinator. [↑](#endnote-ref-2)
3. Find in “**Audit Plan”**, look for MDSAP and who is assigned. [↑](#endnote-ref-3)
4. Find in “**Questions for Quoting Appendix - MDSAP**”, called “**DUNS #**” [↑](#endnote-ref-4)
5. Find in “**Questions for Quoting – MDSAP**” on first page [↑](#endnote-ref-5)
6. Find in customer root folder, “**Current Certificates**”, “**MDSAP Certificate**” or similar. For Scope Extension, check “**Certificate Print Request**” (MS-0023428) or “**Basic audit programme**” (MS-0030309) [↑](#endnote-ref-6)
7. Find in “**Questions for Quoting Appendix – MDSAP**” [↑](#endnote-ref-7)
8. Find in “**Audit Report**”, under “**Description of the Manufacturer**” [↑](#endnote-ref-8)
9. Refer to customer’s “Quality Manual”, look for clauses related to ISO 13485 (4.1.1) [↑](#endnote-ref-9)
10. Find in (1) “**Questions for Quoting Appendix – MDSAP**”, Section 3 “**Scope of Activities**”, (2) “**Certificate Print Request**” (initial certification) or (3) “**Basic Audit Programme**” (MS-0030309) [↑](#endnote-ref-10)
11. Find in “**Questions for Quoting – MDSAP**” under “**Name and location of subcontractors which perform outsourced processes**”. Please check for “**Critical Supplier List**” in folder “Doc from Client”. [↑](#endnote-ref-11)
12. List all past audits (max 3) back to the Certification or Re-Certification Audit. Please check “Basic Audit Programme” (MS-0030309). [↑](#endnote-ref-12)
13. Find in “**Audit Plan**”, at the end in the Comments Section. Confirm with customer’s “Quality Manual” and the “Audit Report (MDD/ISO)”. [↑](#endnote-ref-13)
14. Include details of Stage 1 audit or other relevant pre-audit activities [↑](#endnote-ref-14)
15. Confirm the **Tasks Audited in the “Audit Plan”, Man-day Calculation Record, and MDSAP AU F0008.2.002.** Check for Major Changes in the audit notes from each auditor. There may also be a “**Significant Change Notification**” in the documents from the client. [↑](#endnote-ref-15)
16. Use the following link: <http://ibb.hu/task.php?t=2.1,2.2>. Replace the “2.1,2.2” with the relevant chapter and task numbers that were audited. Include no spaces, only commas. [↑](#endnote-ref-16)
17. Import the NC file then fill details as necessary. [↑](#endnote-ref-17)
18. Discuss if any task was not able to be audited (due to time or similar), and how it is justified. [↑](#endnote-ref-18)