**Important note:** A separate form must be completed for each MDSAP audited site. Please follow the instruction of guidance document “How to complete Basic Data of MDSAP audited facility”.

|  |  |  |  |
| --- | --- | --- | --- |
| DQS MED Reference No. if already known (6 digits) |  | Last saved on:  By (name): |  |

# Audited Facility

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Facility |  | Facility Identifier |  |
| Street Address |  | | |
| Address Details |  | | |
| City |  | ZIP/Postal Code |  |
| State/Province |  | Country |  |

## Audited Facility Contact Person (for Information about the processing of personal data, please scroll down to Appendix 2 or consult 413\_13e\_How to complete Basic Data of MDSAP audited facility)

|  |  |  |  |
| --- | --- | --- | --- |
| Contact Person Name |  | Title |  |
| Email |  | Telephone |  |
| Senior Management at Facility (Name and Title) | |  | |

## Facility Identification Number(s) (if no number or jurisdiction is not applicable, indicate N/A)

|  |  |  |  |
| --- | --- | --- | --- |
| Jurisdiction | Identification Number | Jurisdiction | Identification Number |
| Australia |  | Brazil |  |
| Canada |  | United States |  |
| Japan |  |  |  |

## Legal Manufacturer as specified on product labeling (if different from audited facility) same as Audited Facility (continue with *Section 3)*

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Facility |  | Facility Identifier |  |
| Street Address |  | | |
| Address Details |  | | |
| City |  | ZIP/Postal Code |  |
| State/Province |  | Country |  |

## Identification Number(s) of Legal Manufacturer (if different from auditied facility) same as Audited Facility (continue with Section 3)

|  |  |  |  |
| --- | --- | --- | --- |
| Jurisdiction | Identification Number | Jurisdiction | Identification Number |
| Australia |  | Brazil |  |
| Canada |  | United States |  |
| Japan |  |  |  |

# Audit Criteria

## Jurisdiction and Audit Criteria

**Important note:** MDSAP is based on ISO 13485:2016 as underlying standard.

|  |  |
| --- | --- |
| Jurisdictions and corresponding Medical Device Regulations | |
| **Australia** (skip if not included)   |  | | --- | | Registration numbers listed in the [Australian Register of Therapeutic Goods](https://www.tga.gov.au/australian-register-therapeutic-goods) (ARTG): |   Audited Facility’s role(s) in Australia:  Manufacturer (legal manufacturer)  Australian Sponsor of a Non-Australian Manufacturer  Other, specify:  Applicable regulations: Therapeutic Goods (Medical Devices) Regulations 2002  Schedule 3, Part 1 – Full Quality Assurance System  Schedule 3, Part 4 – Quality Assurance System of Production | |
| **Brazil** (skip if not included)   |  | | --- | | Número do Registro of approvals listed in [Consulta de Produtos](http://consultas.anvisa.gov.br/" \l "/saude/): |   Audited Facility’s role(s) in Brazil:  Brazilian manufacturer   Non-Brazilian manufacturer  Importer (legal representative) of a Non-Brazilian Manufacturer  Other, specify:  Applicable regulations: Federal Law n. 6360/76 RDC ANVISA n. 16/2013 – Good Manufacturing Practices RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009 – Vigilance  RDC ANVISA n. 56/2001 – Essential Requirements for Safety and Effectiveness | |
| **Canada** (skip if not included)   |  | | --- | | Registration numbers of medical device licenses listed in [Medical Devices Active Licence Listing (MDALL)](https://health-products.canada.ca/mdall-limh/index-eng.jsp): |   *Add more lines if necessary 🡪 place cursor into the last line of table and press TAB multiple times*  Audited Facility’s role(s) in Canada:  Manufacturer (legal manufacturer)  Other, specify:  Applicable regulations: Medical Device Regulations SOR/98-282, Part 1 | |
| **Japan** (skip if not included)   |  | | --- | | Numbers of certifications issued by a Registered Certification Body (RCB) or approvals by the Pharmaceuticals and Medical Devices Agency (PMDA) / Ministry of Health, Labor and Welfare (MHLW): |   *Add more lines if necessary 🡪 place cursor into the last line of table and press TAB multiple times*  Audited Facility’s role(s) in Japan:  Japanese Marketing Authorization Holder (MAH)  Registered Manufacturing Site (RMS)  Other, specify:  Applicable regulations: MHLW Ministerial Ordinance No. 169, 2004 – Good Manufacturing Practices ☐ PMD Act | |
| **United States** (skip if not included)   |  | | --- | | Medical devices listed with FDA ([Establishment Registration & Device Listing](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm)): |   *Add more lines if necessary 🡪 place cursor into the last line of table and press TAB multiple times*  Audited Facility’s role(s) for the US:  Complaint File Establishment  Contract Manufacturer  Contract Sterilizer  Foreign Exporter  Foreign Private Label Distributor  Manufacturer  Remanufacturer  Repackager/Relabeler  Reprocessor of Single Use Devices  Specification Developer  U.S. Manufacturer of Export Only Devices  Initial Distributor/Importer  Other, specify:  Applicable regulations: 21 CFR Part 803 – Medical Device Reporting 21 CFR Part 806 – Reports of Corrections and Removals 21 CFR Part 807 (Subparts A to D) – Establishment Registration and Device Listing ☐ 21 CFR Part 820 – Quality System Regulation ☐ 21 CFR Part 821 – Device Tracking | |
| **Europe** (skip if not included)  Audited Facility’s role(s) in Europe:  Manufacturer (legal manufacturer according to MDD/AIMDD/IVDD)  Other, specify:  Applicable regulations: ☐ Medical Device Directive 93/42/EEC (MDD)  ☐ Annex II – Full Quality Assurance System  ☐ Annex V – Quality Assurance System of Production  ☐ Annex VI – Quality Assurance System of Product  ☐ Active Implantable MD Directive 90/385/EEC (AIMDD)  ☐ Annex 2 – Full Quality Assurance System  ☐ Annex 5 – Quality Assurance System of Production  ☐ In Vitro Diagnostic MD Directive 98/79/EC (IVDD)  ☐ Annex IV – Full Quality Assurance System  ☐ Annex VII – Quality Assurance System of Production  Other, specify: | |
| **Other jurisdiction** | Roles in that jurisdiction and applicable regulations |
|  |  |

*Add more lines if necessary 🡪 copy and paste the blank line above as many times as required*

# Scope of Audit Program / Certification

|  |  |  |
| --- | --- | --- |
| Proposed scope of MDSAP audit program (as it appears on the front page of the MDSAP certificate of the legal manufacturer) | | |
| Activities |  | Product categories (each product category must be defined in Appendix 1) |
| Design and development | of |  |
| Manufacturing | of |  |
| Distribution | of |  |
| Installation | of |  |
| Servicing | of |  |

## **Scope of Audit Program / Certification at the Audited Facility** (if different from above) Not Applicable (continue with *Section 7.1)*

|  |  |  |
| --- | --- | --- |
| Activities |  | Product categories (each product category must be defined in Appendix 1) |
| Design and development | of |  |
| Manufacturing | of |  |
| Distribution | of |  |
| Installation | of |  |
| Servicing | of |  |

# Audit Objectives

|  |  |
| --- | --- |
| Languages that are used at the Audited Facility: |  |
| The MDSAP audit should be performed in: | English /  German |
| Will the audit report of this audit be used to apply to the Brazilian Agência National de Vigilância Sanitária (ANVISA) for the purpose of initial certification to Good Manufacturing Practices? | Yes /  No |

## Corporate Information

|  |
| --- |
|  |

## Changes to the quality management system since the last audit

|  |
| --- |
|  |

# Audited Facility Description

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Total staff in the scope of the Audit Program: | |  | | | | |
| Shift Work Office hours: |  | | Activities: |  | Staff: |  |
| Shift 1 weekdays/hours: |  | | Activities: |  | Staff: |  |
| Shift 2 weekdays/hours: |  | | Activities: |  | Staff: |  |
| Shift 3 weekdays/hours: |  | | Activities: |  | Staff: |  |
| Shift 4 weekdays/hours: |  | | Activities: |  | Staff: |  |
| Field work weekdays/hours: |  | | Activities: |  | Staff: |  |

*Add more lines if necessary 🡪 copy and paste one of the above lines above as many times as required*

## Activities under the Audited Facility’s responsibility

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Audited Facility is responsible for the following activities | Performed in-house | If not performed in-house: | | Product categories No. from Appendix 1 |
| Delegated | Outsourced |
| Management | Yes | Yes | Yes | - |
| *Human Resources* | Yes | Yes | Yes | - |
| *Control of the quality management system* | Yes | Yes | Yes | - |
| *Regulatory Affairs* | Yes | Yes | Yes |  |
| *Clinical Affairs* | Yes | Yes | Yes |  |
| Quality Assurance | Yes | Yes | Yes |  |
| *Inspection / Quality Control (product, proceses)* | Yes | Yes | Yes |  |
| *Final product release* | Yes | Yes | Yes |  |
| Design and development | Yes | Yes | Yes |  |
| Production & Service Controls | Yes | Yes | Yes |  |
| *Manufacturing (finished device)* | Yes | Yes | Yes |  |
| *Manufacturing (components, sub-assembly)* | Yes | Yes | Yes |  |
| *Manufacturing (sterilization)* | Yes | Yes | Yes |  |
| *Manufacturing (in-process; other than sterilization)* | Yes | Yes | Yes |  |
| *Manufacturing (device-drug combination)* | Yes | Yes | Yes |  |
| *Manufacturing (device-biologic combination)* | Yes | Yes | Yes |  |
| *Packaging / Labeling* | Yes | Yes | Yes |  |
| *Refurbishment* | Yes | Yes | Yes |  |
| *Installation* | Yes | Yes | Yes |  |
| *Servicing* | Yes | Yes | Yes |  |
| *Storage / Distribution* | Yes | Yes | Yes |  |
| Purchasing Controls | Yes | Yes | Yes |  |
| *Monitoring / Measurement (product, processes)* | Yes | Yes | Yes |  |
| *Import / Distribution (purchased products)* | Yes | Yes | Yes |  |
| Other, specify: | Yes | Yes | Yes |  |

*Add more lines if necessary 🡪 copy and paste the last line above as many times as required*

## Explanations to activities under the Audited Facility’s responsibility

|  |
| --- |
|  |

# Delegated and outsourced processes Not Applicable (skip if no delegated or outsourced processes; see Section 6)

## Related Sites included in the Scope of Audit Program / Certification (to include delegated processes; see Section 6) Not Applicable

|  |  |  |
| --- | --- | --- |
| Related Site | Related Site Facility Identifier | Relationship to Audited Facility |
|  |  | Headquarters  Sister Organization  Subsidiary / Affiliate  Supplier  Client Organization |
|  |  | Headquarters  Sister Organization  Subsidiary / Affiliate  Supplier  Client Organization |

*Add more lines if necessary 🡪 copy and paste the last line above as many times as required*

## Suppliers included in the Scope of Audit Program / Certification (to include outsourced processes; see Section 6) Not Applicable

|  |  |  |
| --- | --- | --- |
| Company Name | Address, City, State/Province, Country, ZIP/Postal Code | Product or services used in activities under the Audited Facility’s responsibility – see Section 6 |
|  |  |  |
|  |  |  |
|  |  |  |

*Add more lines if necessary 🡪 copy and paste the last line above as many times as required*

# Appendix 1 – List of medical devices in the Scope of MDSAP Audit Program

*Use one line for each product category as suggested in the scope of audit program – Section 0*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Product category device or device family | Models included | Category code(s)[[1]](#footnote-1) | Jurisdictions and classification |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |
|  |  | Reg. No. (as applicable):  Brazil ANVISA:  Japan MHLW: | MD  IVD  AIMD  MDS | Australia: I IIa IIb III  Brazil: I II III IV  Canada: I II III IV  Japan: I II III IV  USA: I II III |

*Add more lines if necessary 🡪 copy and paste the last line above as many times as required*

# Appendix 2 – Information about the processing of personal data

We use your data (names of contact persons in the company, addresses, telephone numbers, e-mail addresses) according to article 6 1b) DSGVO for the fulfillment of contracts (certification services) or for the performance of contractual actions (e.g. creation of offers), which take place on request of concerned persons.  
  
For the performance of the order, it is necessary to store the data of the client as well as the relevant legal accreditation information of the company, which are mandatory for the order processing. Contact data is especially needed for the planning of certification procedures and the communication between you and us for the fulfillment of the order. The storage of data and the deletion taking effect are regulated by the legal retention periods.  
  
We are obliged to protect received data and information in paper form and digitally by means of all necessary provisions of organizational and technical kind within the meaning of article 32 DSGVO, so that these are protected against unauthorized processing and use; especially disclosure, change, access and deletion. We do not disclose data and information that becomes known from the fulfillment of the order, unless we have your explicit permission or the contractual relationship relates precisely to these activities (e.g. publication of certifications, inspection of certification documents by the accreditation bodies, approval authorities and authorities).  
  
The inclusion of third parties, as well as the transmission of data and information to the same, which are used by DQS MED for the fulfillment of the contract (e.g. auditors, DQS offices, authorities, accreditation and approval bodies), and those who need these data for the fulfillment of the contract, only takes place, when DQS MED has effectively imposed the same obligations to these third parties. An exception forms a possible necessary disclosure of data to superordinate authorities and approved bodies on basis of article 49 paragraph 1 b) DSGVO, on whose actions we do not have influence. Insofar a risk remains for which DQS MED excludes a liability in the event of damage.  
  
In our general certification and accreditation rules, we have determined specific provisions, which also concern the handling of information and data. This document, in the current valid version, is a binding part of the contract between our customers and us.

You have the following rights with us regarding the person-related data concerning you:

* Right to information about your stored person-related data (Art. 15 DSGVO)
* Right to correction, if the stored data concerning you is faulty, obsolete or otherwise incorrect (Art. 16 DSGVO)
* Right to deletion, if the storage is inadmissible, the purpose of processing fulfilled and therefore the storage no longer necessary or you have withdrawn a given consent for the processing of certain person-related data (Art. 17 DSGVO)
* Right to restriction of processing, if one of the conditions specified in article 18, paragraph 1 a) to D) DSGVO is given (Art. 18 DSGVO)
* Right to transfer the provided person-related data concerning you (Art. 20 DSGVO)
* Right to withdrawal of a given consent (Art. 21 DSGVO), whereby the withdrawal does not affect the legality of the processing previously carried out on basis of the consent (Art. 7 Abs. 3 DSGVO) and
* Right to complaint to a supervisory authority (Art. 77 DSGVO)

We would like to point out, that we need your person-related data for the order fulfillment as mentioned above. If you do not agree or no longer agree with that, your certification order cannot be processed or no longer processed.

Responsible person in the sense of the legal data protection regulations for the processing of your person-related data is: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt, Germany, [www.dqs-med.de](http://www.dqs-med.de), telephone number +49 (0) 69 95427-300.

Our data protection officer is at your disposal in case of questions regarding the processing of your person-related data under: DQS Medizinprodukte GmbH, data protection officer, August-Schanz-Straße 21, 60433 Frankfurt, Germany, [datenschutz@dqs-med.de](mailto:datenschutz@dqs-med.de).

1. NOTE: The current reference list of category codes is included at the end of the guidance document “How to complete Basic Data of MDSAP audited facility”. [↑](#footnote-ref-1)