**Application for Certification AP**

|  |  |
| --- | --- |
| Do not delete any part of this form including instructions | For MEDCERT internal use🡻 |
| Quotation No (if applicable) |       |
| QS/PP-No (see certificate[[1]](#footnote-2)) | QS/PP- | **Ch** | **Rem** |

# The Applicant:

|  |  |  |  |
| --- | --- | --- | --- |
| Company name and address | **[company name and legal form]**[street and No, building/suite as applicable, place/city, province/state, postal code, country] | [ ]  | [ ]  |
| Website | [https://...] | [ ]  | [ ]  |
| Contact person | [name], [position] | [ ]  | [ ]  |
| Phone | +[country code] [area code and number] | [ ]  | [ ]  |
| E-mail | [e-mail address] | [ ]  | [ ]  |
| Company registration | [ ]  copy of company registration attached | [ ]  | [ ]  |
| Former company name and address | [If changed: previous company name][If changed: previous address] | [ ]  | [ ]  |

# The Company is herewith applying to DNV MEDCERT for performance of the following activities \*)

|  |  |  |  |
| --- | --- | --- | --- |
| Initial certification | [ ]  MDR [ ]  MDSAP [ ]  EN ISO 13485 [ ]  TCP | [ ]  | [ ]  |
| Transfer of certification | [ ]  MDR [ ]  MDSAP [ ]  EN ISO 13485 [ ]  TCP | [ ]  | [ ]  |
| Re-certification | [ ]  MDR [ ]  MDSAP [ ]  EN ISO 13485 [ ]  TCP | [ ]  | [ ]  |
| Review of changes | [ ]  MDR [ ]  MDSAP [ ]  EN ISO 13485 [ ]  TCP | [ ]  | [ ]  |
| Other services | [ ]  [specify] | [ ]  | [ ]  |

**\*) Select relevant schemes for requested activities:**

* **MDR**: notified body assessment according to Regulation (EU) 2017/745
* **MDSAP**: certification to ISO 13485 under Medical Device Single Audit Program
* **EN ISO 13485**: quality management system certification to EN ISO 13485
* **TCP**: quality management system audit to ISO 13485 under the Taiwan Technical Cooperation Program

**How to complete this form**:

Expand and complete sections relevant to your selected services. Irrelevant sections: mark accordingly (e.g.: “No MDR”), leave collapsed and skip to next.
**Initial certification** and **Transfer of certification**: provide complete information in relevant sections.
**Re-certification** and **Review of changes**: relevant information should be limited to changes. Sections with no changed information: mark accordingly (“No change”), leave collapsed and skip to next.

**Annex IX MDR - devices that require a Technical Documentation Assessment (TDA) certificate to Annex IX Chapter II**:
1) submit an application for QMS certificate (Annex IX Chapter I+III) covering all your devices, and
2) submit a separate application **for each device that requires a TDA certificate**
The TDA application does not need to repeat information already provided in section 5 of the QMS application covering the same device.

# Scope [ ]  No change; see list of products dated YYYY-MM-DD

|  |  |  |  |
| --- | --- | --- | --- |
| List of products and suppliers | [ ]  attached: form 750504 (spreadsheet) | [ ]  | [ ]  |
| Removed products | [ ]  No [ ]  Yes: [products and reason for removal] | [ ]  | [ ]  |
| New products | [ ]  No [ ]  Yes: products | [ ]  | [ ]  |
| Changes to existing products | [ ]  No [ ]  Yes: [changes and reasons for change]Type of change: [ ]  intended purpose or claims [ ]  design [ ]  design and performance specification [ ]  software [ ]  material [ ]  terminal sterilization method of device [ ]  packaging design with impact for sterilization [ ]  substance (medicinal, animal‑origin etc.)[ ]  other: [specify] | [ ]  | [ ]  |
| New critical suppliers | [ ]  No [ ]  Yes: [supplier and purchased service/product] | [ ]  | [ ]  |
| Relevant existing certificates (not for initial certification) | Schemes: [ ]  MDR [ ]  MDSAP [ ]  EN ISO 13485Certificates: [Certificate No of affected certificates] | [ ]  | [ ]  |

# MDR conformity assessment [ ]  Application does not include MDR  [ ]  No change

|  |  |  |  |
| --- | --- | --- | --- |
| Select conformity assessment procedure covered by this application (select one) An application may only cover one conformity assessment procedure. Complete additional applications, if necessary. | [ ]  **Annex IX (Ch I and III)** – EU Quality Management System[ ]  **Annex XI (Part A)** – EU Quality Assurance SystemThis procedure is only offered for devices up to risk class IIa; please select Annex IX for classes IIb and III.[ ]  **Annex IX (Ch II)** – EU Technical Documentation AssessmentOne technical documentation may only cover one SSCP (summary of safety and clinical performance).  | [ ]  | [ ]  |
| Select regulatory roles of your organisation according to MDR (all that apply) | [ ]  Manufacturer (Art 2 (30)) [ ]  Authorized Rep (Art 2 (32), Art 12) [ ]  System and Procedure Pack Producer (Art 2 (10+11), Art 22) [ ]  Importer (Art 2 (33), Art 13) [ ]  Distributor (Art 2 (34), Art 14) [ ]  Relabeller or Repacker (Art 2 (13), Art 16) [ ]  Reprocessor of single‑use devices (Art 2 (8+39), Art 17) | [ ]  | [ ]  |
| Are any of these devices included? | [ ]  custom‑made devices (Art 2 (3)) [ ]  devices without medical purpose (Art 1 (2), Annex XVI) | [ ]  | [ ]  |
| Your SRN[[2]](#footnote-3) | [format: XX-YY-#########, provide all SRNs if multiple] | [ ]  | [ ]  |

## For manufacturers outside EU/EEA[[3]](#footnote-4) [ ]  Manufacturer is located in EU/EEA

### Authorised representative [ ]  No change

|  |  |  |  |
| --- | --- | --- | --- |
| AR name and address | [company name and legal form][street and No, building/suite as applicable, place/city, province/state, postal code, country] | [ ]  | [ ]  |
| Website | [https://...] | [ ]  | [ ]  |
| Contact person | [name], [position] | [ ]  | [ ]  |
| Phone | +[country code] [area code and number] | [ ]  | [ ]  |
| E-mail | [e-mail address] | [ ]  | [ ]  |
| AR’s SRN | [format: XX-AR-#########] | [ ]  | [ ]  |

### Importer [ ]  No change

|  |  |  |  |
| --- | --- | --- | --- |
| Importer name and address | [company name and legal form][street and No, building/suite as applicable, place/city, province/state, postal code, country] | [ ]  | [ ]  |
| Website | [https://...] | [ ]  | [ ]  |
| Contact person | [name], [position] | [ ]  | [ ]  |
| Phone | +[country code] [area code and number] | [ ]  | [ ]  |
| E-mail | [e-mail address] | [ ]  | [ ]  |
| Importer’s SRN | [format: XX-AR-#########] | [ ]  | [ ]  |

# QMS and organizatioN [ ]  Application only covers Annex IX Ch II (TDA);  see separate QMS application QS-

## General information and changes [ ]  No change

|  |  |  |  |
| --- | --- | --- | --- |
| ISO 13485 - excluded or non-applicable requirements Exclusions and non-applications must be permitted by applicable regulations and justified in your QMS | [ ]  7.3 (design and development) [ ]  7.5.2 (cleanliness) [ ]  7.5.3 (installation) [ ]  7.5.4 (servicing) [ ]  7.5.5+7.5.7 (sterile or re‑sterilization‑required device) [ ]  7.5.9.2 (implantable device) [ ]  7.5.10 (customer property or data) [ ]  7.6 (use of monitoring or measuring devices) [ ]  other: [specify] | [ ]  | [ ]  |
| Applicable jurisdictions (where the company sells devices) | [ ]  EU [ ]  Australia [ ]  Brazil [ ]  Canada [ ]  Japan [ ]  United States [ ]  Taiwan [ ]  other: [specify]  | [ ]  | [ ]  |
| Proposed scope of EN ISO 13485 certificate[[4]](#footnote-5) | [ ]  certification not required, go to next sectionSupply of devices[[5]](#footnote-6) and components/materials[[6]](#footnote-7):[ ] ***Design and development*,** [ ] ***manufacture*,** [ ] ***distribution*,** [ ] ***installation*,** [ ] ***servicing* *of**[devices or components/materials]***Supply of services[[7]](#footnote-8):[ ] ***Provision of [services]*** | [ ]  | [ ]  |
| Changes to certified QMS and organization | [ ]  No [ ]  Yes: [changes and reasons for change]Type of change: [ ]  quality management system [ ]  merger/acquisition [ ]  company name [ ]  company address [ ]  sites/locations included in certification[ ]  other: [specify] | [ ]  | [ ]  |
| Relevant existing certificates (not for initial certification) | Schemes: [ ]  MDR [ ]  MDSAP [ ]  EN ISO 13485Certificates: [Certificate No of affected certificates] | [ ]  | [ ]  |

## MDSAP-specific information [ ]  Application does not include MDSAP  [ ]  No change

|  |  |  |  |
| --- | --- | --- | --- |
| Australia | [ ]  Manufacturer[[8]](#footnote-9) [ ]  Sponsor [ ]  Supplier**TGA Client ID**: [usually 5-6 digits] - obtain from Sponsor in Australia | [ ]  | [ ]  |
| Canada | [ ]  Manufacturer[[9]](#footnote-10) [ ]  Private Label Manufacturer [ ]  Importer [ ]  Distributor [ ]  Regulatory Correspondent**Company ID**: [6 digits] - see [MDALL](https://health-products.canada.ca/mdall-limh/) or [MDEL](https://health-products.canada.ca/mdel-leim/index-eng.jsp) | [ ]  | [ ]  |
| Registered sites[[10]](#footnote-11)Further details in section 5.3 | [ ]  Brazil – [Anvisa database of foreign establishments](https://consultas.anvisa.gov.br/#/empresas/empresasInternacionais/)[ ]  Japan - [PMDA list of registered foreign sites](https://www.pmda.go.jp/review-services/drug-reviews/foreign-mfr/0003.html) [ ]  US - [FDA ER&DL database](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm) | [ ]  | [ ]  |
| Proposed scope of MDSAP certificate[[11]](#footnote-12) | Medical device manufacturers:[ ] ***Design and development*,** [ ] ***manufacture*,** [ ] ***distribution*,** [ ] ***installation*,** [ ] ***servicing* *of**[devices]***Service providers[[12]](#footnote-13):[ ] ***Provision of [services]*****OR**: [ ]  refer to scope statement in section 5.1Included country-specific requirements[[13]](#footnote-14):[ ]  **Australia**: TG(MD) Regs. Sch. 3 Part 1 (full QA) [ ]  **Australia**: TG(MD) Regs. Sch. 3 Part 4 (production QA) [[14]](#footnote-15)[ ]  **Brazil**: RDC Anvisa No 665/2022, 551/2021, 67/2009[ ]  **Canada**: Medical Devices Regs. SOR/98-282 Part 1[ ]  **Japan**: MHLW Ordinance No 169 (2004) and PMD Act[ ]  **United States**: 21 CFR Parts 803, 806, 807, 820 (GMP)[[15]](#footnote-16)[ ]  **United States**: 21 CFR Part 821 (medical device tracking)[[16]](#footnote-17) | [ ]  | [ ]  |

## Site information[[17]](#footnote-18)

### Certification holder site [ ]  No change

|  |  |  |  |
| --- | --- | --- | --- |
| Site name and address | see Applicant’s name and address in section 1 | [ ]  | [ ]  |
| Site activities | [ ]  Management / regulatory affairs[ ]  Design and development[ ]  Manufacture: [ ]  finished device [ ]  components [ ]  sterilization [ ]  process other than sterilization [ ]  packaging/labelling [ ]  storage/warehouse/delivery [ ]  installation [ ]  servicing [ ]  inspection/testing [ ]  final release [ ]  no manufacturing activity at this site[ ]  Purchasing[ ]  other: [specify] | [ ]  | [ ]  |
| Personnel and shift workFTE: full-time equivalent | Total FTE: [number], thereof in shifts: [number]Shifts: [number of shifts] Field workers: [number] | [ ]  | [ ]  |
| Registrations (only for MDSAP)See links in section 5.2 | [ ]  Brazil: **Foreign establishment No**: [format: C######][ ]  Japan: **Registration No**: [format: BG########][ ]  United States: **FEI No**: [usually 6-10 digits] | [ ]  | [ ]  |

### Additional site [ ]  There are no further sites  [ ]  No change

|  |  |  |  |
| --- | --- | --- | --- |
| Site name and address | [company name and legal form][street and No, building/suite as applicable, place/city, province/state, postal code, country] | [ ]  | [ ]  |
| Senior responsible at the site | [name], [position] |  |  |
| Phone | +[country code] [area code and number] |  |  |
| E-mail | [e-mail address] |  |  |
| Site activities | [ ]  Management / regulatory affairs[ ]  Design and development[ ]  Manufacture: [ ]  finished device [ ]  components [ ]  sterilization [ ]  process other than sterilization [ ]  packaging/labelling [ ]  storage/warehouse/delivery [ ]  installation [ ]  servicing [ ]  inspection/testing [ ]  final release [ ]  no manufacturing activity at this site[ ]  Purchasing[ ]  other: [specify] | [ ]  | [ ]  |
| Personnel and shift workFTE: full-time equivalent | Total FTE: [number], thereof in shifts: [number]Shifts: [number of shifts] Field workers: [number] | [ ]  | [ ]  |
| Registrations (only for MDSAP)See links in section 5.2 | [ ]  Brazil: **Foreign establishment No**: [format: C######][ ]  Japan: **Registration No**: [format: BG########][ ]  United States: **FEI No**: [usually 6-10 digits] | [ ]  | [ ]  |

# Documents included in the application

NOTE: We are not allowed to accept your application if documents are not provided as applicable for the requested activity, e.g.: MDR or MDSAP initial assessments. Please provide references of attached documents, e.g.: file names.

## MDR Annex IX Ch I+III Initial certification [ ]  Application does not include Annex IX Ch I+III [ ]  Application is not for MDR initial certification

|  |  |  |  |
| --- | --- | --- | --- |
| Required documents | References (file names) | Ch | Rem |
| 1. A draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure
 |       |[ ] [ ]
| 1. The documentation on the manufacturer's quality management system
 |       |[ ] [ ]
| 1. A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures
 |       |[ ] [ ]
| 1. A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures
 |       |[ ] [ ]
| 1. The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92
 |       |[ ] [ ]
| 1. A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures
 |       |[ ] [ ]
| 1. A documentation on the clinical evaluation plan
 |       |[ ] [ ]
| 1. A description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art
 |       |[ ] [ ]
| 1. The technical documentation of the discussed product referred to in Annexes II and III of MDR
 |       |[ ] [ ]
| 1. The completed List of products and critical suppliers (form 750504)
 |       |[ ] [ ]
| 1. Documentation of the recently conducted internal audit against MDR
 |       |[ ] [ ]
| 1. Documentation of the recently performed management review under MDR
 |       |[ ] [ ]

## MDR Annex IX Ch II Initial or Re-certification [ ]  Application does not include Annex IX Ch II

|  |  |  |  |
| --- | --- | --- | --- |
| Required documents | References (file names) | Ch | Rem |
| The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III. |       |[ ] [ ]

## MDR Annex XI Part A Initial certification [ ]  Application does not include Annex XI Part A [ ]  Application is not for MDR initial certification

|  |  |  |  |
| --- | --- | --- | --- |
| Required documents | References (file names) | Ch | Rem |
| 1. A draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure
 |       |[ ] [ ]
| 1. The documentation on the manufacturer's quality management system
 |       |[ ] [ ]
| 1. A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures
 |       |[ ] [ ]
| 1. A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures
 |       |[ ] [ ]
| 1. The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92
 |       |[ ] [ ]
| 1. A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures
 |       |[ ] [ ]
| 1. A documentation on the clinical evaluation plan
 |       |[ ] [ ]
| 1. A description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art
 |       |[ ] [ ]
| 1. The technical documentation of the discussed product referred to in Annexes II and III of MDR
 |       |[ ] [ ]
| 1. The completed List of products and critical suppliers (form 750504)
 |       |[ ] [ ]
| 1. Documentation of the recently conducted internal audit against MDR
 |       |[ ] [ ]
| 1. Documentation of the recently performed management review under MDR
 |       |[ ] [ ]

## MDR New or additional devices [ ]  Application does not include MDR [ ]  There are no new or additional devices

|  |  |  |  |
| --- | --- | --- | --- |
| Required documents | References (file names) | Ch | Rem |
| The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III. |       |[ ] [ ]

## MDSAP Initial audit [ ]  Application does not include MDSAP [ ]  Application is not for MDSAP initial audit

|  |  |  |  |
| --- | --- | --- | --- |
| Required documents | References (file names) | Ch | Rem |
| The completed List of products and critical suppliers (form 750504) including: * all devices marketed or intended to be marketed in Australia, Brazil, Canada, Japan and the United States. Permissible exclusions are described in point 87 of [MDSAP Q&A](https://www.fda.gov/media/161094/download) and Annex 6 of [MDSAP Audit Approach](https://www.fda.gov/media/157947/download).
* all regulatory representatives in these countries listed as critical suppliers, including (all if multiple): Australian Sponsors, Brazilian Initial Importers, Canadian Regulatory Correspondents (if used, all if multiple), Japanese Marketing Authorization Holders, and U. S. Agents
 |       |[ ] [ ]

# Applicant’s declaration and signature

The applicant agrees to pay all charges and expenses occurring in connection with this certification or conformity assessment process, independent from its result. The DNV MEDCERT General Order and Payment Conditions (form 720403) and Price List (form 520107) apply in their latest up to date versions.

For applications including a conformity assessment procedure under Regulation (EU) 2017/745 (MDR), the applicant hereby declares that:

* no application for the same device-related quality management system or the same device has been lodged with any other notified body.
* no previous application for the same device-related quality management system or the same device was refused by another notified body or withdrawn by the applicant or its authorized representative.
* the applicant commits to always comply with the requirements of the Regulation (EU) 2017/745 that apply to its organization/person or activities.
* the applicant agrees that DNV MEDCERT only accepts documents and correspondence in German or English.

The information already provided in the Questionnaire for Certification (form 720201) is considered as part of this application.

**I hereby confirm that the information provided in this form is correct and complete:**

|  |  |
| --- | --- |
| For [company name and legal form]Place: Date (YYYY-MM-DD): Full name: Position: **(double-click below to sign in Word)** | **How to sign this form**:**Option 1**: sign in Word and submit signed file electronically (preferable)**Option 2**: sign in PDF and submit file electronically together with the Word file \*)**Option 3**: print, sign, and submit scan electronically together with the Word file \*)\*) We require the Word file for our further processing. |

# Application review - for MEDCERT internal use, applicant please leave this section collapsed

**Instruction**:
If Word file is signed -> check above that applicant name and date above signature correspond to name and date in the signature; your edits will remove signature. Approver can also sign in Word. In case of further changes the last signature will always be removed, so please always ensure previous signature initials and dates are included.

FS applications without changes -> check by ACB -> escalate to DCB as necessary.

All other applications -> check by ACB -> review and approval/on hold/refusal by DCB.

When updating a signed application -> save as new variant, do not overwrite.

## ACB check result

|  |  |  |
| --- | --- | --- |
| Application 720202, signed | [ ]  **CHECKED – OK** | [ ]  **Rem**: [explain all Rem items][ ]  **ESCALATE TO DCB** |
| ACB date/sign | [initial] [YYYY-MM-DD] | double-click to sign in Word  |

## DCB IA/Transfer/Change or escalated review [ ]  N/A for FS without changes

|  |  |  |
| --- | --- | --- |
| Item to review: | If checked->go to next: | If checked->comment (explanation, follow-up action)->go to next |
| Application 720202, signed | [ ]  **all** **Ch:** no comments | [ ]  **Rem**: [explain all Rem items] |
| Questionnaire 720201, reviewed | [ ]  **Yes** | [ ]  **No**: [comment] |
| Cert agreement 720401, signed | [ ]  **Yes** | [ ]  **No**: [comment] |
| Transfer agreement 720305, signed | [ ]  **Yes** [ ]  **No transfer** | [ ]  **No**: [comment] |
| List of devices 750504 on file | comment mandatory-> | [ ]  **Yes:** [ENAIO name] [ ]  **No**: [comment] |
| MDR: specific consultation procedures under Annex IX | [ ]  **None** [ ]  **No MDR** | [ ]  **Section** **5.1** CECP/scrutiny[ ]  **Section** **5.2** medicinal substance consultation[ ]  **Section** **5.3.2** animal-origin consultation – Reg 722/2012[ ]  **Section** **5.4a** absorbed/dispersed via orifice consultation[ ]  **Section** **5.4b** absorbed by body consultation |
| MDR: pre-application valid | [ ]  **Yes** [ ]  **No MDR** | [ ]  **No**: [application still valid? -> justify] |
| MDR: obstacles in EUDAMED | [ ]  **No** [ ]  **No MDR** | [ ]  **Yes**: [explain obstacles] |
| Codes plausible [MDCG 2019-14][[18]](#footnote-19) | [ ]  **Yes** | [ ]  **No**: [comment] |
| Finished products are devices  | [ ]  **Yes** [ ]  **None** | [ ]  **No**: [comment] |
| Components/mat. device-related | [ ]  **Yes** [ ]  **None** | [ ]  **No**: [comment] |
| Services are device-related | [ ]  **Yes** [ ]  **None** | [ ]  **No**: [comment] |
| MDR: borderline [MDCG 2022-5] | [ ]  **No**  [ ]  **No MDR** | [ ]  **Yes**: [comment] |
| MDR: class plausible [B&C manual][[19]](#footnote-20) | [ ]  **Yes**  [ ]  **No MDR** | [ ]  **No**: [comment] |
| MDR: selected procedure plausible | [ ]  **Yes** [ ]  **No MDR** | [ ]  **No**: [comment] |
| MDR IX(II): related IX(I) is on file | [ ]  **This is not IX(II)** | [ ]  **Yes**, see QS-      [ ]  **No**: [comment] |
| MDSAP: RA requirements plausible | [ ]  **Yes** [ ]  **No MDSAP** | [ ]  **No**: [comment] |
| Sites information plausible | [ ]  **Yes** | [ ]  **No**: [comment] |
| Changes affecting certificates | [ ]  **No changes** | [ ]  **No**, already covered in: [Cert No][ ]  **Yes**, change needed in: [Cert No] |
| Transfer review completed | [ ]  **No transfer** | [ ]  **Completed**, see: AU     [ ]  **Not yet completed**, [NB/AO/CB] cert [Cert No] |
| Application decision | [ ]  **APPROVED** | [ ]  **ON HOLD**: [actions to complete][ ]  **REFUSED**: issue refusal letter and notify EUDAMED |
| Planned scope | [ ]  **No change** | [ ]  **New or changed**, see Annex at the end |
| DCB date/sign | [initial] [YYYY-MM-DD] | double-click to sign in Word  |

### COOR create work orders/assessment program

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Stage 1 | [ ]  N/A | WO-      | AU   | [comment] |
| SA-Transfer | [ ]  N/A | WO-      | AU   | [comment] |
| TDA | [ ]  N/A | WO-      | AU   | [comment] |
| Sterilisation | [ ]  N/A | WO-      | AU   | [comment] |
| Audit IA/PS/FS/SA | [ ]  N/A | WO-      | AU   | [comment] |
| COOR date/sign | [initial] [YYYY-MM-DD] | double-click to sign in Word  |

### CUS administration

|  |  |  |  |
| --- | --- | --- | --- |
| Order confirmation | [ ]  N/A | [ENAIO name] | [comment] |
| Refusal letter + EUDAMED | [ ]  N/A | [ENAIO name] | [comment] |
| Checklists | [ ]  N/A | [send date] | [comment] |
| Request transfer files | [ ]  N/A | [send date] | [comment] |
| COOR date/sign | [initial] [YYYY-MM-DD] | double-click to sign in Word  |

# Attachment – for MEDCERT internal use

**DCB reviewed scope statements** – double-click to edit, delete unnecessary files

|  |  |
| --- | --- |
| **QMS** |  |
| **TDA (separate application)** |  |

1. This number is the same as the numeric digits of the Certificate No. of your corresponding certificate, the 4 or 5 digits preceding “GB” or “DE”. [↑](#footnote-ref-2)
2. Single Registration Number (Art 31 MDR). [↑](#footnote-ref-3)
3. If you have multiple ARs or Importers, duplicate the Authorised representative or Importer section using the “+” button. [↑](#footnote-ref-4)
4. If you need multiple scope sentences (e.g.: *Manufacture of A, B, C; distribution of D, E, F*), multiply the respective template using the “+” button. [↑](#footnote-ref-5)
5. **Medical devices**: must be described using appropriate generic terms, e.g.: nomenclature terms such as GMDN or EMDN. [↑](#footnote-ref-6)
6. **Components/materials**: must include for what medical devices or kinds of medical devices they are intended, e.g.: *printed circuit boards for monitoring devices*. [↑](#footnote-ref-7)
7. **Services**: must include for what medical devices or kinds of medical devices they are intended, e.g.: *ethylene oxide sterilization of injection and infusion devices*. [↑](#footnote-ref-8)
8. According to the Australian legal definition “Manufacturer”. [↑](#footnote-ref-9)
9. According to the Canadian legal definition “Manufacturer”. [↑](#footnote-ref-10)
10. It is helpful to use a translating web browser when reviewing websites in Portuguese or Japanese. [↑](#footnote-ref-11)
11. If you need multiple scope sentences (e.g.: *Manufacture of A, B, C; distribution of D, E, F*), multiply the respective template using the “+” button. [↑](#footnote-ref-12)
12. Services may include contract design and development, contract manufacture, or other services. They must be related to devices. [↑](#footnote-ref-13)
13. It is mandatory to include all participating jurisdictions where you are holding or intending to obtain marketing authorizations for medical devices. Exclusions from this obligation are described in [MDSAP Q&A](https://www.fda.gov/media/161094/download) Question 87 and [MDSAP Audit Approach](https://www.fda.gov/media/157947/download) Annex 6:

**Australia**: mandatory if you have devices if classes Is, Im, IIa, IIb or III – see [ARTG](https://compliance.health.gov.au/artg/); voluntary for class I

**Brazil**: mandatory if you handle registered devices of classes III or IV – see [Anvisa medical devices register](https://consultas.anvisa.gov.br/#/saude/); voluntary for classes I and II

**Canada**: mandatory if you have licenced devices of classes II-IV – see [MDALL](https://health-products.canada.ca/mdall-limh/); voluntary for class I

**Japan**: mandatory if you handle approved or certified devices of classes II-IV; voluntary for class I

**Unites States**: mandatory if you handle listed devices that are not GMP-exempt – see [ER&DL](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm), click on your device listing, then on 3-letter product code [↑](#footnote-ref-14)
14. Acceptable for devices up to Australian class IIa. [↑](#footnote-ref-15)
15. 21 CFR Part 820 (GMP) can only be excluded for devices which are "GMP exempt" according to their product classification code in the [FDA ER&DL database](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm). [↑](#footnote-ref-16)
16. Required if you have been issued a “tracking order” by the FDA for your device. [↑](#footnote-ref-17)
17. If you have multiple additional sites, duplicate the Additional site section using the “+” button. [↑](#footnote-ref-18)
18. Reference added in Rev 2. [↑](#footnote-ref-19)
19. Reference added in Rev 2. [↑](#footnote-ref-20)