

413_13e_How to complete Basic Data of MDSAP audited facility (V5.0)

This guidance explains how to complete the Basic Data form required for organizations audited under the Medical Device Single Audit Program (MDSAP). Explanation of every section of the Basic Data of MDSAP audited facility form starts from a new page.

Important note: A separate form must be completed for each MDSAP audited site.

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(to include delegated processes; see Section **Error! Reference source not found.**) ☐ **Not Applicable**

7.2 Suppliers included in the Scope of Audit Program / Certification (to
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found.**) ☐ **Not Applicable**

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

Appendix 2 – Reference list of Medical Device Category Codes

General information on MDSAP and Basic Data

What is MDSAP and DQS MED's role in it?

The MDSAP allows to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the program, including: Australia's Therapeutic Goods Administration of Australia (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada (HC), Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), and the United States' Food and Drug Administration (FDA).

DQS Medizinprodukte GmbH is a MDSAP Auditing Organization (AO) authorized to provide MDSAP audits and issue MDSAP certificates to organizations eligible to be audited under MDSAP.

Further information on MDSAP is available on the MDSAP Webpage. We specifically recommend to consult the following sources:

[Questions and Answers on the Medical Device Audit Program](#) (sections A and C),

[MDSAP Audit Procedures and Forms](#) ("Audit Model" and "Companion Document"),

Training in [CDRH Learn](#) ("Postmarket Activities" → "Inspection/Global Harmonization")

As currently planned, any manufacturer of medical devices will be eligible to undergo an audit under the MDSAP. However, each regulatory authority may establish exclusion criteria for manufacturers meeting certain conditions if deemed necessary or when limited by legislation.

What is Basic Data and why do we need it?

Certification bodies are required to take certain information about organizations to be audited into consideration when planning audit and certification activities. DQS calls such information "Basic Data". This form is specific for the MDSAP program.

When do we require you to submit this Basic Data?

You will be required to submit Basic Data when you request an MDSAP audit for your organization for the first time. Additionally, we will require you to re-submit Basic Data in the following cases:

when we are starting to prepare for your upcoming regular audit (i.e. surveillance or recertification audit); **AND**

if you have informed us about a change in your organization or the certified QMS that may be relevant to our auditing and certification activities.

What are the main differences between Basic Data of MDSAP audited facility and other Basic Data?

Unlike other Basic Data forms of DQS MED, a separate copy of this form is required for each facility to be audited under MDSAP.

Unlike Basic Data forms required for ISO 13485, MDD or CMDCAS certification, no separate form is required to list medical devices covered by the MDSAP audit. Instead, this form's Appendix 1 is used to list all product categories of medical devices covered in the scope of MDSAP audit program/certificate.

Is it required to submit other additional Basic Data forms?

Yes, if your organization also requests certification in other programs, such as MDD and/or ISO 13485.

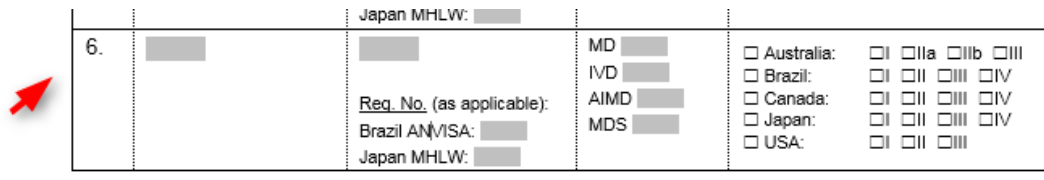
Important note on completing the Basic Data form

In some sections (e.g. 3.1, 4.1, 4.2, 6, 6.1, 7 and Appendix 1) you will be required to add more lines to tables as necessary.

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

In such cases, please do as follows to add additional lines:

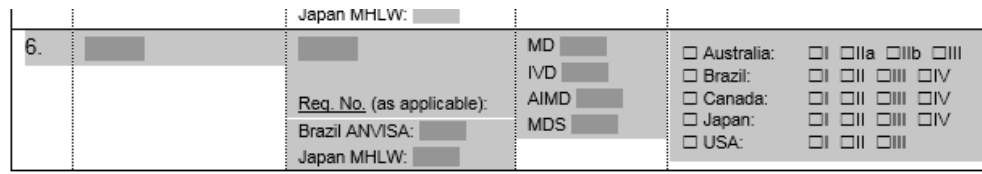
1. Place the mouse cursor on the left of the last table line:



6.		Japan MHLW: <input type="text"/>	MD <input type="text"/> IVD <input type="text"/> AIMD <input type="text"/> MDS <input type="text"/>	<input type="checkbox"/> Australia: <input type="checkbox"/> I <input type="checkbox"/> IIa <input type="checkbox"/> IIb <input type="checkbox"/> III <input type="checkbox"/> Brazil: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Canada: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Japan: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> USA: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III
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Add more lines if necessary → copy and paste the last line above as many times as required

2. Left-click to select the line:

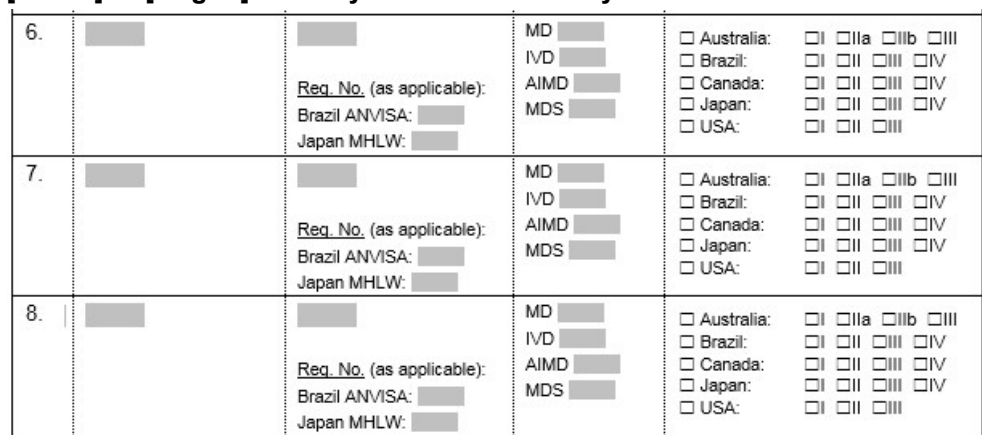


6.		Japan MHLW: <input type="text"/>	MD <input type="text"/> IVD <input type="text"/> AIMD <input type="text"/> MDS <input type="text"/>	<input type="checkbox"/> Australia: <input type="checkbox"/> I <input type="checkbox"/> IIa <input type="checkbox"/> IIb <input type="checkbox"/> III <input type="checkbox"/> Brazil: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Canada: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Japan: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> USA: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III
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Add more lines if necessary → copy and paste the last line above as many times as required

3. Press [Ctrl+C] or [Strg+C] to copy the line to clipboard.

4. Press [Ctrl+V] or [Strg+V] as many times as necessary to insert additional lines:



6.		Japan MHLW: <input type="text"/>	MD <input type="text"/> IVD <input type="text"/> AIMD <input type="text"/> MDS <input type="text"/>	<input type="checkbox"/> Australia: <input type="checkbox"/> I <input type="checkbox"/> IIa <input type="checkbox"/> IIb <input type="checkbox"/> III <input type="checkbox"/> Brazil: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Canada: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Japan: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> USA: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III
7.		Japan MHLW: <input type="text"/>	MD <input type="text"/> IVD <input type="text"/> AIMD <input type="text"/> MDS <input type="text"/>	<input type="checkbox"/> Australia: <input type="checkbox"/> I <input type="checkbox"/> IIa <input type="checkbox"/> IIb <input type="checkbox"/> III <input type="checkbox"/> Brazil: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Canada: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Japan: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> USA: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III
8.		Japan MHLW: <input type="text"/>	MD <input type="text"/> IVD <input type="text"/> AIMD <input type="text"/> MDS <input type="text"/>	<input type="checkbox"/> Australia: <input type="checkbox"/> I <input type="checkbox"/> IIa <input type="checkbox"/> IIb <input type="checkbox"/> III <input type="checkbox"/> Brazil: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Canada: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Japan: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> USA: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III

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

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.dqsglobal.com, 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.

Explanation of the content to be provided when completing the Basic Data

Header / identification

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

The 6-digit client number assigned by DQS MED to a client organization. It can be found on various records or as part of "Reg. No." on certificates issued by DQS MED.

Leave this space empty, if you do not know or do not yet have your DQS MED Reference No.

Last saved on

Date, on which the Basic Data file was last saved.

By (name)

Indicate the name(s) of the individual(s) who completed the form.

Section 2. Audited Facility

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

Name of Facility

Specify the name of the organization as it would appear on any certification document, and if different, the name under which it is incorporated, or if applicable, any other name under which it is registered with the Regulatory Authorities.

Organization Group of people and facilities with an arrangement of responsibilities, authorities and relationships.

Example: Company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof.

Notes:

1. The arrangement is generally orderly.
2. An organization can be public or private.
3. This definition is valid for the purposes of quality management system standards. The term "organization" is defined differently in ISO/IEC Guide 2. (ISO 9000:2015)

The term "organization" in the context of this document refers to the entity that was audited. An organization may be a "manufacturer".

Facility Identifier

Unique number used to identify the facility.

If no specific facility identifier has been assigned by the AO, the facility management must apply a free D-U-N-S (Data Universal Numbering System) Number prior to the end of the audit. The D-U-N-S Number is a unique, 9-digit identifier for businesses and is generated by Dun & Bradstreet specific for each physical facility location of your business. To apply for a free D-U-N-S Number, please follow the link: <http://www.dnb.com/get-a-dunsnumber.html>.

2.1 Audited Facility Contact Person

Name:		Title:	
Telephone:		Email:	
Senior Management at Facility (Name and Title):			

Identifies the individual of the audited organization responsible for interacting with the Auditing Organization for audit planning and associated follow-up activities. This individual's normal work location may or may not be the site audited.

2.2 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			

Where applicable, specify the set of jurisdiction-specific identifiers issued by the MDSAP Regulatory Authorities to the audited facility. Additional jurisdictions and corresponding Facility identification numbers may be added in the empty fields.

If no number exists, indicate “N/A” (not available).

Country-specific Facility Identification Numbers	
Australia	<p>TGA assigns a Client ID and a Location ID for each facility. Please indicate the facilities Client ID. The TGA Client ID for a legal manufacturer should be known by the manufacturer or could be obtained from their Australian Sponsor. The Sponsor can request this information from the TGA (devices@tga.gov.au).</p> <p>If the identifier is not known then the field in the Basic Data may be left blank (please indicate “N/A”).</p>
Brazil	<p>ANVISA assigns a 7-digit registration number only to initial importers in Brazil who are responsible for medical device authorization. This registration number equals to the first 7 digits of the medical device product authorization number (“Número do Registro”). ANVISA does not assign any specific number to foreign medical device facilities.</p>
Canada	<p>Health Canada assigns a 6-digit Company ID number only to facilities who hold medical device licenses or medical device establishment licenses. This number can be found in the online license listing – see in “Company ID” field of licenses listed in MDALL or MDEL. Health Canada does not assign any specific number to other medical device facilities.</p>
Japan	<p>PMDA/MHLW assigns to RMS a 10 digit number consisting of alphabets (2 digits) followed by 8 digit numerals. The registration numbers of foreign RMS can be found on the registration certificate for foreign medical device manufacturer (upper left corner) or in the pdf/zip files linked on Publication of Foreign Manufacturers.</p>
United States	<p>FDA assigns an Establishment Registration Number to any medical device facility that is required to register. This number can be found in the online database – see in “Registration Number” field of entries listed in Establishment Registration & Device Listing. All audited facilities under MDSAP program that are subject to the United States requirements would have such a number.</p>

2.3 Legal Manufacturer as specified on product labeling (if different from audited facility)

☐ **same as Audited Facility** (continue with *Section Error! Reference source not found.*)

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

Legal Manufacturer

Identifies the organization that has the legal responsibility for the product.

Note: if the audited facility makes devices for several manufacturers, this should be clarified in sections 4.2 (in an additional note under “Related Site”) and/or 6.3 (in additional notes under “Corporate Information”), as appropriate. In such a case, include as an attachment, the list of all related manufacturers and corresponding devices.

Manufacturer¹ (MDSAP definition)

Any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Notes:

1. This ‘natural or legal person’ has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.
2. The manufacturer’s responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.
3. ‘Design and/or manufacture’, as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.
4. Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.
5. Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.
6. An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labeling, is not considered a manufacturer.
7. To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

¹ [MDSAP AU P0019.003](#), Section 1.5

Same as Audited Facility

If the Audited Facility is itself Manufacturer (see definition above), check the box and skip to Section 3.

Facility Identifier

Unique number used to identify the facility.

For details, see section 2.0.

2.4 Identification Number(s) of Legal Manufacturer (if different from audited facility)

☐ **same as Audited Facility** (continue with Section **Error! Reference source not found.**)

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

For details, see section 2.2 „Facility Identification Number“ above.

Same as Audited Facility

If the Audited Facility is itself the Manufacturer (see definition section 2.3), check the box and skip to Section 3.

Section 3. Audit Criteria

3.1 Jurisdiction and Audit Criteria

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

Jurisdictions and corresponding Medical Device Regulations	
<input type="checkbox"/> [Country] → if not included, skip to next jurisdiction	
<div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> Numbers of registrations/approvals/licenses/certifications...: </div>	
Audited Facility's role(s) in [Country]: <div style="display: inline-block; vertical-align: top; margin-left: 20px;"> <input type="checkbox"/> [Possible role] <input type="checkbox"/> [Possible role] <input type="checkbox"/> [...] <input type="checkbox"/> Other, specify: </div>	
Applicable regulations: <div style="display: inline-block; vertical-align: top; margin-left: 20px;"> [Regulation that is always applicable (without checkbox)] <input type="checkbox"/> [Regulation that may or may not be applicable (with checkbox)] </div>	
<input type="checkbox"/> [...]	
Other jurisdiction	Roles in that jurisdiction and applicable regulations

Standards

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

Jurisdictions

Select the box corresponding to the countries where the manufacturer commercializes or intends to commercialize medical devices, and to which regulations the manufacturer claims compliance.

The MDSAP participating countries are Australia, Brazil, Canada, Japan and United States. You **must** select any of these MDSAP participating country countries, if:

- the manufacturer commercializes or intends to commercialize medical devices in that country; **AND**
- medical devices, which the manufacturer commercializes or intends to commercialize are in the scope of MDSAP audit and should be included in the MDSAP certificate

Numbers of registrations/approvals/licenses/certifications

Indicate numbers of medical device approvals in Australia, Brazil, Canada and Japan (as applicable). The guidance in the form directs you on type of approval identification, per country.

<u>Country-specific medical device numbers of registrations/approvals/licenses/certifications</u>	
Australia	<p>A medical device is approved for marketing in Australia, if it is listed in the Australian Register of Therapeutic Goods (ARTG). To look up the listing:</p> <ul style="list-style-type: none"> use the above link to go to ARTG click on the button "Search the ARTG" enter the manufacturer, product, or Australian sponsor name in the search string copy all relevant ARTG IDs into the form
Brazil	<p>A medical device is approved for marketing in Brazil, if it is listed in ANVISA's Consulta de Produtos. To look up the listing:</p> <ul style="list-style-type: none"> use the above link to go to "Consultas" enter relevant information such as product name ("Nome do Produto"), or search by the name of the Brazilian importer ("CNPJ") you may be requested to validate that the search is not automated click on the button "Consultar" copy all relevant "Registro" numbers into the form
Canada	<p>A medical device of class II, III or IV is approved for marketing in Canada, if it is included in an active medical device license. Such licenses are listed on in Medical Devices Active License Listing (MDALL). To look up an active license:</p> <ul style="list-style-type: none"> use the above link to go to MDALL click on "Active License Search" choose a search option, e.g. "Company name" of the manufacturer enter the search text in the search string click on the button "Search" if multiple manufacturers appear, select click on the relevant one's ID copy all relevant license numbers into the form
Japan	<p>A medical device is approved in Japan, if:</p> <ul style="list-style-type: none"> it is certified by a Registered Certification Body (RCB) [for "designated controlled medical devices"]; OR it is approved by the Regulatory Authority PMDA/MHLW <p>To obtain certification/approval numbers, contact the Manufacturing Authorization Holder (MAH) who is the holder of certification/approval. Comprehensive lists of approved products (pdf files) can be found here.</p>

Audited Facility's role(s)

Depending on the country, there are various roles Audited Facility may have in the subject jurisdiction. Indicate all applicable roles per country. The following roles may be applicable.

<u>Country-specific audited facility roles</u>	
Australia	<p><u>Manufacturer²</u> ("legal manufacturer" – Australian definition) of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.</p> <p><u>Australian Sponsor³</u> in relation to therapeutic goods, means:</p> <ul style="list-style-type: none"> (a) a person who exports, or arranges the exportation of, the goods from Australia; or (b) a person who imports, or arranges the importation of, the goods into Australia; or (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); <p>but does not include a person who:</p> <ul style="list-style-type: none"> (d) exports, imports or manufactures the goods; or (e) arranges the exportation, importation or manufacture of the goods; <p>on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.</p>
Brazil	<p><u>Manufacturer⁴</u> (Brazilian definition) any person who designs, manufacture, assemble or process a finished product, including those who perform functions by contract for sterilizing, labeling, packaging.</p> <p>Note: Unlike the Australian, Canadian or European definitions, the Brazilian definition of "manufacturer" does not mean the sole/unique responsible for the product as indicated on the product labeling. There may be multiple facilities having the role of "manufacturer" by Brazilian definition for one registered product.</p> <p><u>Importer⁵</u> (legal representative) the importer is considered the legal representative of the international manufacturer in Brazil and shall be authorized by ANVISA to import, store, and distribute medical devices. In the case of outsourcing the storage, the importer does not need authorization for this activity.</p>
Canada	<p><u>Manufacturer⁶</u> (Canadian definition) means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.</p>
Japan	<p><u>Marketing Authorization Holder⁷</u> means a person who resides in Japan and is granted a license for marketing from a prefectural government.</p> <p><u>Registered Manufacturing Site⁸</u> a medical device manufacturing site which conducts one of the designated manufacturing processes listed below shall be registered: (a) Main Designing, (b) Main assembly, (c) Sterilization, and (d) Domestic storage before final release.</p>

² Australian Therapeutic Goods Act 1989, Section 41BG

³ Australian Therapeutic Goods Act 1989, Section 3(1)

⁴ [RDC ANVISA n. 665/2022](#) (Brazilian GMP), Section 1.2.9

⁵ [MDSAP AU G0002.1](#) (Companion Document), Page 17

⁶ [CMDR SOR/98-282](#) (Canadian Medical Devices Regulations), Section 1

⁷ PMD Act (Japanese law) 23-2.1, cited from [MDSAP AU G0002.1](#) (Companion Document), Page 18

⁸ PMD Act (Japanese law) 23-2-3.1, 23-2-4, cited from [MDSAP AU G0002.1](#) (Companion Document), Page 18

United States ⁹	<p><u>Complaint File Establishment</u> - Maintains complaint files as required under 21 CFR 820.198</p> <p><u>Contract Manufacturer</u> - Manufactures a finished device to another establishment's specifications.</p> <p><u>Contract Sterilizer</u> - Provides a sterilization service for another establishment's devices.</p> <p><u>Foreign Exporter</u> - Exports or offers for export to the United States (U.S.), a device manufactured, prepared, propagated, compounded, or processed in a foreign country, including devices originally manufactured in the United States. A foreign exporter must have an establishment address outside the U.S.</p> <p><u>Manufacturer (US definition)</u> - Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.</p> <p style="padding-left: 40px;">Note: Unlike the Australian, Canadian or European definitions, the US definition of "manufacturer" does not mean the sole/unique responsible for the product as indicated on the product labeling. There may be multiple facilities having the role of "manufacturer" by the US definition for one listed product.</p> <p><u>Remanufacturer</u> - Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.</p> <p><u>Repackager</u> - Packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding shipping containers).</p> <p><u>Relabeler</u> - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.</p> <p><u>Reprocessor of Single Use Device</u> - Performs remanufacturing operations on a single use device.</p> <p><u>Specification Developer</u> - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing. This includes establishments that, in addition to developing specifications, also arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.</p> <p><u>U. S. manufacturer of export only devices</u> - Manufactures medical devices that are not sold in the U.S. and are manufactured solely for export to foreign countries.</p> <p><u>Initial Importer</u> - Any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. The initial importer must have a physical address in the United States staffed by individuals responsible for ensuring the compliance of imported devices with all applicable FDA laws and regulations.</p>
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Applicable regulations

As required, specify the applicable regulatory documents considered and against which the manufacturer claims compliance.

For example, US 21 CFR 821 only applies if the manufactured devices are subject to device tracking. See the MDSAP Certification Document Requirements MDSAP AU P0026¹⁰ – section 9 – for specific considerations on the inclusion or exclusion of 21 CFR Part 820 as audit criterion.

Jurisdictions that are not pre-listed in the form may be added as an "Other Jurisdiction". In such a case, the relevant Regulation(s) should also be specified.

⁹ Content taken from [Who Must Register, List and Pay the Fee](#) as last updated 04/04/2016

¹⁰ [MDSAP AU P0026](#) (Certificate Document Requirements)

This is an overview of applicable Medical Device Regulations of MDSAP participating countries.

<u>Country-specific applicable Medical Device Regulations</u>	
Australia	Therapeutic Goods (Medical Devices) Regulations 2002 , Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [if design controls are part of the certification]; OR Schedule 3 Part 4 – Production Quality Assurance Procedure [if design controls are excluded from the certification]
Brazil	Federal Law n. 6360/76 and RDC ANVISA resolutions: RDC ANVISA n. 665/2022 (Good Manufacturing Practices) RDC ANVISA n. 23/2012 (Vigilance) RDC ANVISA n. 67/2009 (Vigilance) RDC ANVISA n. 56/2001 (Essential Requirements for Safety and Performance)
Canada	Medical Devices Regulations (SOR 98/282) – Part 1
Japan	MHLW Ministerial Ordinance 169 , Article 4 to Article 68 PMD Act (as applicable)
United States	21 CFR 820* (Quality System Regulation) 21 CFR 803 (Medical Device Reporting) 21 CFR 806 (Reports of Corrections and Removals) – Subchapter H 21 CFR 807 (Registration and Listing) – Subparts A to D 21 CFR 821 (Medical Device Tracking) (where applicable) <p>* When United States requirements are audited, 21 CFR 820 is applicable unless it has been demonstrated to the Auditing Organization that the audited organization is exempt (by FDA regulation) from all Quality System Regulation requirements other than 21 CFR 820.180 and 198.</p>

Section 4. 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)
<input type="checkbox"/> Design and development	of	
<input type="checkbox"/> Manufacturing	of	
<input type="checkbox"/> Distribution	of	
<input type="checkbox"/> Installation	of	
<input type="checkbox"/> Servicing	of	

Statement of activities and range of devices to appear in certificate. The scope statement consists of activities and devices. When the scope of certification is extensive, it may be included in an attached document.

Activities

All the activities covered by the scope of certification statement should be relevant to the devices covered. In wording the scope statement of the certification document, only the following terms may be used:

- **Design and development**
- **Manufacture**
- **Production**
- **Servicing**
- **Installation**
- **Distribution**

All certification documents must include the terms “manufacture” or “production” in the overall scope statement. If design controls are included, the terms “design” or “design and development” must be included in the scope statement.

Product categories (devices)

Complete table in Appendix 1 at the end of the form to determine product categories covered in the scope statement.

The scope statement shall list all devices covered by certificate. In doing so, generic device group descriptors may be used. The listing shall be specific enough to determine whether a given device (e.g. pediatric bone biopsy needle, PFO closure device, gamma camera, etc.) is covered without resorting to the inclusion of trade-names, models, or device identifiers. Broad terms such as “medical device”, “components”, “accessories”, or “parts” shall not be used. Specific descriptions shall be used for such items that are provided by the manufacturer of a medical device.

Note: Each product category must be defined in Appendix 1.

4.1 Scope of Audit Program / Certification at the Audited Facility (if different from above)

☐ **Not Applicable** (continue with [Section 0](#))

Activities		Product categories (each product category must be defined in Appendix 1)
<input type="checkbox"/> Design and development	of	
<input type="checkbox"/> Manufacturing	of	
<input type="checkbox"/> Distribution	of	
<input type="checkbox"/> Installation	of	
<input type="checkbox"/> Servicing	of	

Statement of activities and range of devices specifically pertaining to the audited facility that is to appear in a certification document.

Not Applicable

This sub-section is not applicable if the audited facility is the only facility included in the scope of audit program/certification. Check the box and skip to section 4.2.

Activities

See guidance in section 4.0.

More specific terms for activities may be included in the sub-scope statements for individual locations. (e.g. assembly, packaging, sterilization, quality control, warehousing, etc.)

In case more specific terms are required, expand the table to add additional lines.

Product categories (devices)

See guidance in section 4.0.

Section 5. Audit Objectives – relevant information

All languages that are used at the Audited Facility:	
The MDSAP audit should be performed in:	<input type="checkbox"/> English / <input type="checkbox"/> German
Will the audit report of this audit be used to apply to the Brazilian Agência Nacional de Vigilância Sanitária (ANVISA) for the purpose of initial certification to Good Manufacturing Practices (bGMP)?	<input type="checkbox"/> Yes / <input type="checkbox"/> No

All languages used at the Audited Facility

Indicate language(s) used by the Audited Facility's staff during the audit activities.

The MDSAP audit should be performed in

Indicate the language – English or German – in which DQS MED should conduct the audit activities.

Note: The audit documentation (audit report, etc.) will always be issued in English.

Will the audit report of this audit be used to apply to ANVISA for the purpose of initial certification to Good Manufacturing Practices?

Where an MDSAP audit report is used for the purpose of initial GMP certification by ANSISA, the audit must be a full initial or recertification audit, and not a surveillance audit. Please indicate, Yes or No, so that we can appropriately plan the required type of audit in the audit program.

5.1 Corporate Information

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Organization information should be clarified in cases where a manufacturer has multiple names or identities. This clarification also extends to relevant relationships with sister, parent, and daughter companies, including subsidiaries, acquisitions, business units, and joint ventures under the scope of the QMS, audit program, or certification. When preparing this section, auditors should be mindful to frame the explanation in the context of the QMS being audited and its associated scope of activities and devices.

Note: if the audited facility makes devices for several manufacturers, this should be clarified in this section, as appropriate. In such a case, include as an attachment, the list of all related manufacturers and corresponding devices.

5.2 Changes to the quality management system since the last audit

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Any relevant changes to the QMS since the last audit. This includes, but is not limited to:

- organizational changes (company name, contact person, field of business activity, companies size, ownership, consultants, ...)
- new products/services
- essential processes
- sites/facilities
- suppliers

Section 6. Audited Facility Description

Total staff in the scope of the Audit Program:					
<input type="checkbox"/> 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:

Total staff in the scope of the Audit Program

Total number of staff affiliated to the audited facility and involved in the scope of the Audit Program, regardless whether usually working at the audited facility or at a remote location.

Shift Work

Select if applicable, for activities included in the scope of the audit program or scope of certification. If applicable, specify for each shift, including the office/administration and field/remote staff:

the operating weekdays and hours, e.g.: “*Mo-Fr 9-5*”

activities of the respective shift, e.g. “*passivation*”

the number of staff

6.1 Activities under the Audited Facility's responsibility

Audited Facility is responsible for the following activities (product-related)	Performed in-house	Outsourced	Product categories No. from Appendix 1
<input type="checkbox"/> [Activity]	<input type="checkbox"/> Yes / <input type="checkbox"/> No	<input type="checkbox"/> Yes / <input type="checkbox"/> No	N/A [if not product-related]
<input type="checkbox"/> [Activity]	<input type="checkbox"/> Yes / <input type="checkbox"/> No	<input type="checkbox"/> Yes / <input type="checkbox"/> No	[product-related]

Audited Facility is responsible for the following activities (product-related)

Select all activities implemented by or on behalf of the audited facility applicable to the products within the scope of the audit or the scope of certification.

Performed in-house and/or Outsourced/delegated

Specify for each applicable activity if they are performed in house and/or at an external facility on behalf of the audited facility.

Note: an intermediate activity necessary for the realization of the product and performed by an external facility, even if not directly purchased by the audited facility, should be listed and identified as outsourced.

For example, if facility ABC manufactures the finished products – all operations except for sterilization – for a separate legal manufacturer XYZ. The sterilizing process is applied by a separate organization MNO. Both descriptions of activities of ABC and XYZ should identify that “Sterilization” is an activity included in the scope of the audit and that it is an outsourced activity.

Delegated

An “delegated process” is a process that the organization has identified as being needed for its operations and quality management system (QMS), but is carried out by an internal provider inside the managerial control of the QMS of your organization.

Outsourced

An “outsourced process” is a process that the organization has identified as being needed for its operations and quality management system (QMS), but is carried out by an external provider outside the managerial control of the QMS of your organization.

Product categories

Indicate product categories, to which the respective activity applies, by entering numbers of product categories from the table in Appendix 1.

6.2 Explanations to activities under the Audited Facility's responsibility

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Any relevant information to clarify the activities under the Audited Facility's responsibility as stated above.

Section 7. Delegated and outsourced processes

☐ **Not Applicable** (skip if no delegated or outsourced processes; see Section **Error! Reference source not found.**)

Not applicable

Select the box if no activity (see section 6) in the context of the scope of Audit Program/Certification (see section 4) was outsourced/delegated to another facility/site.

7.1 Related Sites included in the Scope of Audit Program / Certification (to include delegated processes; see Section Error! Reference source not found.)

☐ Not Applicable

Related Site	Related Site Facility Identifier	Relationship to Audited Facility
		<input type="checkbox"/> Headquarters <input type="checkbox"/> Sister Organization <input type="checkbox"/> Subsidiary / Affiliate <input type="checkbox"/> Supplier <input type="checkbox"/> Client Organization
		<input type="checkbox"/> Headquarters <input type="checkbox"/> Sister Organization <input type="checkbox"/> Subsidiary / Affiliate <input type="checkbox"/> Supplier <input type="checkbox"/> Client Organization

Not applicable

Select the box if no activity (see section 6) in the context of the scope of Audit Program/Certification (see section 4) was delegated to another facility (see section 6).

Related Site

This section applies when an organization has several facilities included in the Scope of the Audit Program or Scope of Certification.

For example, a critical supplier may be included in the Scope of the Audit Program although it should not appear in the certificate.

Note: if the audited facility makes devices for several manufacturers, this should be clarified in sections this section and/or section 6.3 (in additional notes under “Corporate Information”), as appropriate. In such a case, include as an attachment, the list of all related manufacturers and corresponding devices.

Related Site Facility Identifier

Unique number used to identify the facility.

If no specific facility identifier has been assigned by the AO, the facility management must apply a free D-U-N-S (Data Universal Numbering System) Number prior to the end of the audit. The D-U-N-S Number is a unique, 9-digit identifier for businesses and is generated by Dun & Bradstreet specific for each physical facility location of your business. To apply for a free D-U-N-S Number, please follow the link: <http://www.dnb.com/get-a-dunsnumber.html>.

Relationship to Audited Facility

Select in the drop-down menu the relationship existing between the related site and the audited facility:

Headquarters designates a facility owning the audited facility (several “headquarters” may be identified);

Subsidiary / Affiliate designates any facility owned by the audited facility;

Sister Organization designates any other facility belonging to the same corporate organization;

Supplier designates an organization outside the audited facility's organization, which provides any product or service and is included in the scope of the audit program;

Client Organization is only applicable when auditing a critical supplier, to designate the ordering facility on behalf of which the audit is performed.

7.2 Suppliers included in the Scope of Audit Program / Certification (to include outsourced processes; see Section **Error! Reference source not found.**)

☐ **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 Error! Reference source not found.

Not applicable

Select the box if no activity (see section 6) in the context of the scope of Audit Program/Certification (see section 4) was outsourced to another facility (see section 6).

Company Name, Address

Specify the legal name and the physical address of the Critical Supplier. If the Critical Supplier operates several facilities, the information included in this section should correspond to the facility directly involved in the provision of the purchased products or services to the audited facility.

Products or Services used in Audited Facility's responsibility

Specify the products or services obtained from the external source relevant in the context of activities in the responsibility of the Audited Facility (see section 6).

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

No.	Product category device or device family	Models included	Category code(s)	Jurisdictions and classification
1.		<p>Reg. No. (as applicable):</p> <p>Brazil ANVISA:</p> <p>Japan MHLW:</p>	<p>MD</p> <p>IVD</p> <p>AIMD</p> <p>MDS</p>	<p><input type="checkbox"/> Australia: <input type="checkbox"/> I <input type="checkbox"/> IIa <input type="checkbox"/> IIb <input type="checkbox"/> III</p> <p><input type="checkbox"/> Brazil: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV</p> <p><input type="checkbox"/> Canada: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV</p> <p><input type="checkbox"/> Japan: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV</p> <p><input type="checkbox"/> USA: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III</p>

Identification of all medical devices (or medical device families) included in the scope of audit program/certification by product category.

No. (line number)

The line numbers will increase automatically in the form as the new lines are inserted into the table. The auto-numeration may be removed and replaced by manual numeration, but each line should have a unique number.

These line numbers must be used to reference product categories in section 6.1 of the form (description of audited facility).

Product category

Product categories will be used for the determination of the scope of audit program/certification (section 4).

A separate product category shall be used to describe each device or device family:

Device family¹¹ a group of medical devices that differ only in shape, color, flavor or size, that have the same design and manufacturing process and that have the same intended use

If there are multiple devices of the same kind, i.e. only different in shape, color, flavor or size, they should be described as one device family using just one product category.

In doing so, generic device group descriptors may be used. The listing shall be specific enough to determine whether a given device (e.g. pediatric bone biopsy needle, PFO closure device, gamma camera, etc.) is covered without resorting to the inclusion of trade-names, models, or device identifiers. Broad terms such as “medical device”, “components”, “accessories”, or “parts” shall not be used. Specific descriptions shall be used for such items that are provided by the manufacturer of a medical device.

Models included

Identify models (by reference number, article number, device identifier or similar) of medical devices covered by the product category.

¹¹ In analogy to „medical device family“ according to [CMDR SOR/98-282](#) Section 1.

Broader model ranges may be indicated, e.g. using wildcards, if they would completely fall under the same product category.

Examples: 22xxx (for all sequences starting with “22” and having 5 digits)
 4LN* (for all sequences starting with “4LN” of any length)
 101200-101299 (for all numbers between 101200 and 101299)

ANVISA and MHLW required that any devices covered in the scope statement that are approved for marketing in Brazil and/or Japan are included in the scope of audit program/certification by their approval numbers. Therefore, indicate all Brazilian ANVISA registrations and Japanese MHLW approvals for all models covered by product category (see section 3.1).

Category Codes

Indicate the category code(s) of the product category. This typically includes just one MD, IVD or AIMD code and may include multiple MDS codes.

The reference list of category codes is provided below, at the end of this instruction.

Jurisdictions and classification

Indicate all countries, to which the device or device family in this product category are sold or planned to be sold.

For each selected country, indicate the risk class of the device or device family according to the country-specific regulation.

Appendix 2 – Reference list of Medical Device Category Codes

MD General non-active, non-implantable medical devices	
MD 0101	Non-active device for anaesthesia, emergency and intensive care
MD 0102	Non-active device for injection, infusion, transfusion and dialysis
MD 0103	Non-active orthopaedic and rehabilitation devices
MD 0104	Non-active medical devices with measuring function
MD 0105	Non-active ophthalmologic devices
MD 0106	Non-active instruments
MD 0107	Contraceptive medical devices
MD 0108	Non-active device for disinfecting, cleaning and rinsing
MD 0109	Non-active device for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
MD 0110	Non-active medical devices for ingestion
MD Non-active implants	
MD 0201	Non-active cardiovascular implants
MD 0202	Non-active orthopaedic implants
MD 0203	Non-active functional implants
MD 0204	Non-active soft tissue implants
MD Non-active devices for wound care	
MD 0301	Bandages and wound dressing
MD 0302	Suture material and clamps
MD 0303	Other medical devices for wound care
MD Non-active dental devices and accessories	
MD 0401	Non-active dental equipment and instruments
MD 0402	Dental materials
MD 0403	Dental implants
MD General active medical devices	
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
MD 1102	Respiratory devices, devices incl. hyperbaric chambers for oxygen therapy, inhalation anaesthesia
MD 1103	Devices for stimulation or inhibition
MD 1104	Active surgical devices
MD 1105	Active ophthalmologic devices
MD 1106	Active dental devices

MD 1107	Active devices for disinfection and sterilisation
MD 1108	Active rehabilitation devices and active prostheses
MD 1109	Active devices for patient positioning and transport
MD 1110	Active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
MD 1111	Software
MD 1112	Medical gas supply systems and parts thereof

MD Devices for imaging

MD 1201	Imaging devices utilising ionizing radiation
MD 1202	Imaging devices utilising non-ionizing radiation

MD Monitoring devices

MD 1301	Monitoring devices of non-vital physiological parameters
MD 1302	Monitoring devices of vital physiological parameters

MD Devices for radiation therapy and thermo therapy

MD 1401	Devices utilising ionizing radiation
MD 1402	Devices utilising non-ionizing radiation
MD 1403	Devices for hyperthermia / hypothermia
MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)

IVD In Vitro Diagnostic medical devices

IVD 0501	Clinical chemistry
IVD 0502	Haematology
IVD 0503	Immunochemistry (Immunology)
IVD 0504	Molecular biology
IVD 0505	Pregnancy and ovulation
IVD 0506	Specimen receptacles
IVD 0507	Microbiology
IVD 0508	Infectious Immunology
IVD 0509	Histology / Cytology
IVD 0510	Genetic Testing
IVD 0600	In Vitro diagnostics instruments and software

AIMD Active implantable medical devices

AIMD 0101	AIMD for stimulation / inhibition
AIMD 0102	AIMD delivering drugs or other substances
AIMD 0103	AIMD substituting or replacing organ functions

AIMD 0200	Radioactive seeds for interstitial radiotherapy
MDS 7001-7010 Specifics of medical devices other than In Vitro Diagnostic medical devices	
MDS 7001	Devices incorporating medicinal substances
MDS 7002	Devices utilising tissues of animal origin
MDS 7003	Devices incorporating derivates of human blood
MDS 7006-1	Ethylene oxide gas sterilization
MDS 7006-2	Moist heat sterilization
MDS 7006-3	Sterilization by aseptic processing
MDS 7006-4	Radiation sterilization e.g. gamma, x-ray, electron beam
MDS 7006-5	Other sterilization method
MDS 7006-6	Low temperature steam and formaldehyde sterilisation
MDS 7007	Devices utilising micromechanics
MDS 7008	Devices utilising nanomaterials
MDS 7009	Devices utilising biological active coatings and/or materials or being wholly or mainly absorbed
MDS 7010	Devices incorporating / utilising / controlled by software
MDS 7205-7210 Specifics of In Vitro Diagnostic medical devices	
MDS 7205	IVD incorporating / utilising / controlled by software
MDS 7206-1	Ethylene oxide gas sterilization
MDS 7206-2	Moist heat sterilization
MDS 7206-3	Sterilization by aseptic processing
MDS 7206-4	Radiation sterilization e.g. gamma, x-ray, electron beam
MDS 7206-5	Other sterilization method
MDS 7206-6	Low temperature steam and formaldehyde sterilisation
MDS 7207	IVD utilising micromechanics
MDS 7208	IVD utilising nanomaterials
MDS 7209	IVD utilising biological active coatings and/or materials or being wholly or mainly absorbed
MDS 7210	IVD utilising materials of human origin