Briefing Note

Quality Assurance Requirements for the Procurement of Oxygen Therapy Medical Devices

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Background

The medical devices referred to in this document are primarily oxygen therapy medical devices procured with the Global Fund resources in response to the COVID-19 pandemic. These include but are not limited to ventilators, oxygen generation plants, concentrators, pulse oximeters, oxygen masks, flowmeters and analyzers. The full list is available in Annex 1 of the Interim Guidance on Interim Quality Assurance (QA) Requirements for the Procurement of COVID-19 Medical Devices.[1]

All medical devices must meet the safety and performance requirements which are established by the markets within which they are registered or approved. The classifications and requirements differ based on the regulatory jurisdiction. This guidance document is based on the requirements of the Regulatory Authorities of the Founding Members of the Global Harmonization Task Force (GHTF)[2] namely Japan, Canada, United States, European Union and Australia.

There are two main routes to ensure procurement of medical devices that meet quality, safety and performance requirements. The first route consists of the verification of the quality, safety and performance of the medical device by requesting the provision of data compiled in a technical file, reviewing the whole dossier submitted and performing all regulatory actions in order to validate compliance with applicable regulations (product testing, auditing, etc.) as per the established regulatory pathways. Such assessment is performed by the national regulatory authority in each respective jurisdiction, having full responsibility and authority to allow the introduction of a medical device on the national market or by a delegate authority on its behalf (i.e., notified bodies in Europe). Such assessment requests require an important body of knowledge, in-depth experience in the standards to be applied and robust processes. Further guidance is available on the World Health Organization (WHO) website.[3]

The second route is the reliance mechanism to an existing regulatory authority – or an existing group of regulatory authorities – to ensure indirectly the quality, safety and performance of the medical device. In such cases the required documentation is of a different nature, it includes certificates or approvals issued by the regulatory authority in which the reliance mechanism is based on. In this second route, less competencies and experience are required. This is the route which is elaborated in this Briefing Note in line with the Global Fund's Interim Guidance on Interim QA Requirements for the Procurement of COVID-19 Medical Devices.[4]

[1] See https://www.theglobalfund.org/media/11060/covid19_interimqualityassurancerequirements-medicaldevice_guidance_en.pdf
[2] See https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf
[3] See https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1&isAllowed=y
[4] See https://www.theglobalfund.org/en/covid-19/health-product-supply/quality-assurance/

Purpose

The primary purpose of this Briefing Note is to provide guidance for ensuring that COVID19 medical devices procured with C19RM funds meet the Global Fund quality assurance requirements stated in the guidance on Interim Quality Assurance Requirements for the Procurement of COVID-19 Medical Devices.

Reference to Global Fund Policy

As per the Interim Guidance, Principal Recipients (PRs) or the Procurement Agent acting on their behalf shall ensure that medical devices of Higher Risk (class C and class D) meet either one of the following standards:

- Prequalified by the WHO Prequalification Programme.
- Authorized for use by one of the Regulatory Authorities of the Founding Members of the GHTF.
- Recommended for use by the Expert Review Panel.

In addition, COVID-19 Medical Devices eligible for procurement using Global Fund resources may be:

- Products approved pursuant to the WHO Emergency Use Listing (EUL) procedures; and/or
- Products approved pursuant to any other emergency procedure set up by one of the Regulatory Authorities of the Founding Members of the GHTF.

Please refer to **Annex 5** for more information on emergency procedures.

Scope

This Briefing Note is used for the qualification of medical devices used in the management of COVID-19 as defined in the Interim Guidance on Interim Quality Assurance Requirements for the Procurement of COVID-19 Medical Devices.

This Briefing Note provides detailed guidance to ensure compliance with the specific QA requirements for COVID-19 class C and D medical devices procured with Global Fund resources.

The QA Team is supportive of a due diligence process for class A and B medical devices to ensure some level of assurance of quality as per the guidance provided in this document.

This Briefing Note is not applicable to medical devices which are covered by other QA requirements outlined in any of the Global Fund quality assurance policies or in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (e.g., condoms and core personal protective equipment).

Limitations

Because Global Fund QA requirements are established based on a reliance mechanism to stringent regulatory mechanisms, this document should not be seen as a tool to assess the quality and performance of the medical device which needs in-depth knowledge and experience of standards relevant to these products and related regulatory processes.

The guidance in this Briefing Note is based on the collection of regulatory information issued by stringent regulators. Medical device regulation is a continuous improvement process and subject to changes and/or revisions. Therefore, this Briefing Note and accompanying annexes shall be considered as reference only and should not be relied upon for compliance with specific regulatory purposes. The Global Fund accepts no responsibility for any inaccuracies, omissions or errors in this Briefing Note and the accompanying annexes. The primary sources of information should be consulted for up-to-date and authoritative guidance.

In case of any doubt around the applicability of this Briefing Note to a specific procurement process, please contact the QA team on:
healthproductsqualityassurance@theglobalfund.org

Responsibilities

This Briefing Note is aimed at recipients of the Global Fund resources or to a procurement agency acting on their behalf. The main users are staff members who are in charge of Quality Assurance within procurement departments/institutions to ensure the quality, safety and efficacy of the medical devices being purchased.

Description of the Activities / Procedure

The activities outlined in this section are to be carried out by the PR's specialists or those of the procurement agent acting on their behalf.

Register request

The Procurement Specialist identifies a new oxygen therapy medical device(s) for COVID-19 treatment and forwards it to the QA Specialist who will ensure eligibility with the Global Fund QA requirements.

QA pathway

A decision is made by the QA Specialist if the approval to procure is made in reliance to the stringent regulatory framework or by dossier review. If the reliance to a stringent regulatory framework is used, please continue as per this Briefing Note. If full dossier review is required, please follow specific internal procedures (not covered by this Briefing Note).

To facilitate such decision, the QA Specialist can take benefit of the Global Fund list of eligible products published and regularly updated on the Global Fund website.[5]

Request the documentation

Depending on his/her knowledge, experience and resources, the QA Specialist may envisage different strategies such as:

- Request all relevant evidence of compliance for each jurisdiction as described in Annex 1. Europe and Australia, Annex 2. Canada, Annex 3. United States and Annex 4. Japan.
- Request relevant documented evidence of compliance for at least one of the above jurisdictions.

Screen documentation

The QA Specialist screens the provided documentation for completeness and communicates with the Procurement Specialist if any documentation is missing or not to standard.

Evaluate documentation

The QA Specialist assesses the documentation for compliance with the relevant regulation and risk category. In particular, the QA Specialist:

- Checks the labelling and the instructions for use to identify the main product information as follows:
    - Product name.
    - Product type and product code (if any).
    - Intended use/purpose (medical versus non-medical).

[5] https://www.theglobalfund.org/en/covid-19/health-product-supply/quality-assurance/

- Supplier name as well as any ID No.
- Distributor or Authorized Representative.
- Logo or mark (CE) related to the regulatory pathway.

- Refers to relevant annexes for details on the documentation that needs to be reviewed depending on the type of product assessed and the available regulatory approvals.

In specific circumstances, the Interim Guidance document allows reliance on emergency procedures set up by stringent regulatory bodies. In such cases, the following can be reviewed:

- Products approved pursuant to the WHO Emergency Use Listing (EUL) procedures; and/or
- Products approved pursuant to any other emergency procedure set up by one of the Regulatory Authorities of the Founding Members of the GHTF.[6]

In most cases, the submission includes pictures of the packaging and labeling. In some exceptional cases, the QA Specialist may request a sample of a small medical device to review labeling and packaging.

Analysis of sample

In most instances, the quality attributes of medical devices cannot be tested at the procurement stage. The QA Specialist can implement risk-based principles and focus on certain quality attributes such as sterility or Ethylene Oxide desorption which can be analyzed by an accredited laboratory.

The basic principles for testing health products can be applied such as:

- Sampling by an independent sampling agent.
- Testing by an independent ISO 17025-accredited laboratory or Good Laboratory Practices[7] certified having the test methods in its scope of accreditation.
- Testing according to the international standards claimed or the approved specifications and methods.

In case of testing, the QA Specialist will check the results issued following the analysis against the specifications to conclude on compliance.

[6] Namely the regulatory authorities of the United States, the European Union, Japan, Canada and Australia. See https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf
[7] The OECD Principles of Good Laboratory Practice (GLP) - http://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm

Product approval

The QA Specialist decides based on the collected evidence to approve the product, documents this in the report and informs the relevant departments.

Product surveillance

Depending on the product surveillance strategy implemented, the QA Specialist can decide to launch some verification activities of the products procured at the design stage of the products life cycle along the supply chain. Aside from any punctual decision needed based on the results of such verification, the outcome of such activities should be taken into consideration for the requalification of the products.

Product requalification cycle

The QA Specialist will perform a re-evaluation of the approved item in a frequency as described as per its internal procedure but no less than every two years to keep the approval status.

If information suggests that the product has been modified, a request for update of the documentation should be initiated. The QA Specialist reviews the acceptability of the product, decides on its re-approval / disapproval and updates the relevant records/list of eligible products.

Abbreviations

ARTG	Australian Register of Therapeutic Goods
COA	Certificate of Analysis
ERP	Expert Review Panel
EUL	Emergency Use Listing
GSPR	General Safety and Performance Requirements
BN	Briefing Note
ISO	International Organization for Standardization
OOS	Out of Specification
PDI	Pre-Delivery Inspection
PPM	Pooled Procurement Mechanism
PQT	Prequalification Team
PR	Principal Recipient
PSA	Procurement Service Agent
PSM	Procurement and Supply Management
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authority
TGA	Therapeutics Goods Administration
US FDA	United States Food & Drug Administration
WHO	World Health Organization

References

- Guide to Global Fund Policies on Procurement and Supply Management of Health Products (June 2021) https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf
- Interim Guidance on Interim Quality Assurance Requirements for the Procurement of COVID-19 Medical Devices (version dated 27 October 2021) https://www.theglobalfund.org/media/11060/covid19_interimqualityassurancerequirements-medicaldevice_guidance_en.pdf
- European Medical Device Regulations 2017/745 MDR: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
- The Australian Therapeutic Goods (Medical Devices) Regulations 2002: https://www.legislation.gov.au/Details/F2021C00390
- TGA Declaration of conformity templates, 20 May 2021 https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices
- Schedule 1 (Section 6) of Medical Device Regulations (SOR98-282): https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-13.html#h-1022100
- 21 CFR Part 800-1099 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=800&CFRPartTo=1099
- Access Global Unique Device Identification Database (GUDID) https://accessgudid.nlm.nih.gov/
- 510(k) Premarket notification database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
- Pharmaceuticals and Medical Devices (PMD) Act (Japan) https://www.emergobyul.com/resources/articles/white-paper-japan-new-pharmaceutical-medical-devices-act

Annex 1. Europe and Australia

The classification and reference for Europe has been defined per the European Medical Devices Regulations (MDR), which is largely equivalent to the European Medical Devices Directive (MDD) for the types of devices covered in this guidance document.

Annex 1.1. Medical Device Classification and Reference for Europe and Australia

Medical Device	Classification	Guidance (Requirements)	Reference	
			Europe [8]	Australia [9]
Medical gas cylinder, portable	Class IIa	The classification of compressed oxygen or compressed medical air, with valves and regulators, is Class IIa unless it is connected to an active device (e.g. patient-interactive ventilator or respirator), in which case it will be Class IIb.	Rule 2	Rule 2.2 (1)(c)(2)
Oxygen plant	Class IIb	Active device used to channel or store oxygen for introduction to patient.	Rule 2	Rule 2.2 (1)(c)(2)
Airway	Class I	Transient use (<60 min) **OR** short-term use (60min – 30 days).	Rule 5	Rule 3.1 (2)(a) **OR** Rule 3.1 (2)(b)(ii)
	Class IIa	Long term (>30 days) use.	Rule 5	Rule 3.1 (2) (c) (ii)
CO2 Detector (Colorimetric End Tidal)	Class I	N/A	Rule 1	Rule 2.1
Cricothyrotomy	Class IIa	Transient use (<60min) **OR** short-term use (60min – 30days).	Rule 6/7	Rule 3.2 (1)(2) **OR** Rule 3.3 (1)(2)
Endotracheal Tube	Class IIa	Short-term insertion (60min – 30days).	Rule 5	Rule 3.1 (2)(b)(i)
	Class IIb	Long term insertion (>30days).	Rule 5	Rule 3.1 (2)(c)(i)
Endotracheal Tube Introducer	Class I	N/A	Rule 5	Rule 3.1 (2)(a)
Flow splitter	Class IIa	N/A	Rule 2	Rule 2.2 (1)(c)(ii)(2)
Flowmeter, Medical O2, Gas Cylinder	Class IIa	If directly administering oxygen to the patient.	Rule 12	Rule 4.4 (1)
	Class IIb	If controlling or monitoring the performance or influencing the performance of an active device **OR** if directly administering oxygen to the patient in a potentially hazardous situation (e.g. ICU).	Rule 9 **OR** Rule 12	Rule 4.2 (3) **OR** Rule 4.4 (2)
	Class IIa	If directly administering oxygen to the patient	Rule 12	Rule 4.4 (1)

[8] European Medical Device Regulations 2017/745 MDR: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[9] The Australian Therapeutic Goods (Medical Devices) Regulations 2002: https://www.legislation.gov.au/Details/F2021C00390

Medical Device	Classification	Guidance (Requirements)	Reference	
			Europe [8]	Australia [9]
Flowmeter, medical O2, Terminal (wall) Unit	Class IIb	If controlling or monitoring the performance or influencing the performance of an active device **OR** if directly administering oxygen to the patient in a potentially hazardous situation (e.g. ICU)	Rule 9 **OR** Rule 12	Rule 4.2 (3) **OR** Rule 4.4 (2)
Humidifier	Class IIa	N/A	Rule 9	Rule 4.2 (1)
Infusion Giving Set	Class IIa	N/A	Rule 2	Rule 2.2 (1)(c) / Rule 2.2(2)
Laryngoscope	Class I	N/A	Rule 5	Rule 3.1 (2)(a)
Nasal Cannula	Class I	Short term use, up to 30days.	Rule 5	Rule 3.1 (2)(b)(ii)
Nasal Catheter	Class I	Short term use, up to 30days.	Rule 5	Rule 3.1 (2)(b)(ii)
Nasal Prong	Class I	Short term use, up to 30days.	Rule 5	Rule 3.1 (2)(b)(ii)
Oxygen mask	Class I	N/A	Rule 2	Rule 2.1
Pulse Oximeter Probes	Class IIa	If monitoring vital physiological processes of a patient	Rule 10	Rule 4.3 (2)(c)
	Class IIb	If variations in the readings result in immediate danger to the patient e.g. variations in cardiac performance. Or where the patient is in immediate danger, e.g. ICU.	Rule 10	Rule 4.3(3)(a)
Resuscitator	Class I	If not connected to active device	Rule 2	Rule 2.1
	Class IIa	If connected to active device	Rule 2	Rule 2.2 (1)(c)(ii) (2)
Suction Device	Class IIa	N/A	Rule 12	Rule 4.4 (1)
	Class IIb	If intended for use in potentially hazardous situations, with regard to the substances involved, part of the patient's body and the characteristics of the device.	Rule 12	Rule 4.4 (2)
Tubing	Class IIa	N/A	Rule 2 **OR** Rule 5	Rule 2.2 (1)(c)(ii) (2)
Mechanical Ventilation	Class IIa	If used for conscious and spontaneously breathing patients only, where failure to deliver the appropriate dosage characteristics is not potentially hazardous.	Rule 12	Rule 4.4 (1)
	Class IIb	If used for unconscious or non-spontaneously breathing patients in intensive-care units	Rule 12	Rule 4.4 (2)
Non-Invasive Ventilation	Class IIa	If used for conscious and spontaneously breathing patients only, where failure to deliver the appropriate dosage characteristics is not potentially hazardous.	Rule 12	Rule 4.4 (1)
	Class IIb	If used for unconscious or non-spontaneously breathing patients in intensive-care units	Rule 12	Rule 4.4 (2)

Medical Device	Classification	Guidance (Requirements)	Reference	
			Europe [8]	Australia [9]
Oxygen Analyser	Class I	If not administering to the patient	Rule 13	Rule 4.1
Oxygen Concentrator	Class IIa	If used for conscious and spontaneously breathing patients only, where failure to deliver the appropriate dosage characteristics is not potentially hazardous.	Rule 12	Rule 4.4 (1)
	Class IIb	If used for unconscious or non-spontaneously breathing patients in intensive-care units	Rule 12	Rule 4.4 (2)
Pulse Oximeter	Class IIa	If monitoring vital physiological processes of a patient	Rule 10	Rule 4.3 (2)(c)
	Class IIb	If variations in the readings result in immediate danger to the patient e.g. variations in cardiac performance. Or where the patient is in immediate danger, e.g. ICU.	Rule 10	Rule 4.3(3)(a)
Surge suppressor	Not a medical device			
Voltage stabilizer	Not a medical device			
Blood Gas Analyser	Class IIa	If monitoring vital physiological processes of a patient	Rule 10	Rule 4.3 (2)(c)
	Class IIb	If variations in the readings result in immediate danger to the patient e.g. variations in cardiac performance. Or where the patient is in immediate danger, e.g. ICU.	Rule 10	Rule 4.3(3)(a)
Electrocardiogram (ECG) digital monitor and recorder	Class IIa	If monitoring vital physiological processes of a patient	Rule 10	Rule 4.3 (2)(c)
	Class IIb	If variations in the readings result in immediate danger to the patient e.g. variations in cardiac performance. Or where the patient is in immediate danger, e.g. ICU.	Rule 10	Rule 4.3(3)(a)
Electronic drop counter	Class IIa	N/A	Rule 13	Rule 4.4 (1)
Infusion Pump	Class IIb	N/A	Rule 12	Rule 4.4 (2)
Patient monitor	Class IIa	If monitoring vital physiological processes of a patient	Rule 10	Rule 4.3 (2)(c)
	Class IIb	If variations in the readings result in immediate danger to the patient e.g. variations in cardiac performance. Or where the patient is in immediate danger, e.g. ICU.	Rule 10	Rule 4.3(3)(a)
Thermometer	Class IIa	N/A	Rule 10	Rule 4.3 (2)(c)
Ultrasound	Class IIa	If diagnosing/ vital physiological processes of a patient	Rule 10	Rule 4.3 (2)(c)

Medical Device	Classification	Guidance (Requirements)	Reference	
			Europe [8]	Australia [9]
	Class IIb	If variations in the readings result in immediate danger to the patient e.g. variations in cardiac performance. Or where the patient is in immediate danger, e.g. ICU.	Rule 10	Rule 4.3(3)(a)
X-ray: Equipment	Class IIb	N/A	Rule 10	Rule 4.3 (a) (b)

Annex 1.2. Summary of Requirements – Europe

Classification	EU Declaration of Conformity	CE Mark	QMS Certificate (MDD & MDR)	Product Assessment (MDD)	Product Assessment (MDR)	Notified Body Assessment
Class I	✓	✓	N/A	N/A	N/A	N/A
Class IIa	✓	✓	✓	N/A	✓	✓
Class IIb	✓	✓	✓	✓	✓	✓

Annex 1.3. Evidence of Compliance – Europe

A European Declaration of Conformity is required for all medical devices placed on the market in Europe. By drawing up the Declaration of Conformity, the manufacturer assumes responsibility for compliance with the requirements of the referenced regulations. Further details on the requirements for the EU Declaration of Conformity are included in Annex 1.4.

Class I Medical Devices

Class I medical devices have the lowest perceived risk. Manufacturers of such devices are required to self-declare the conformity of their products by preparing a European Declaration of Conformity.

Note: This pathway does not apply to Class I devices that are intended to be provided sterile.

Class I (Sterile) and Class IIa Medical Devices

Class Is and Class IIa devices are considered low-to-medium risk devices and are hence subject to conformity assessment processes including assessment of technical documentation by a European Notified Body. In this process, the manufacturer submits the appropriate Quality Management System and Technical File documentation to the Notified Body for assessment. Upon successful review, the Notified Body will issue EC certificate to the applicable annexes of the European Medical Device Directives/Regulations (MDD/MDR).

Refer to **Table 1** for the appropriate conformity assessment evidence for Class Is and Class IIa medical devices.

Class IIb Medical Devices

Class IIb devices are considered medium-to-high risk devices and are subject to conformity assessment processes including assessment of technical documentation by a European Notified Body to obtain a CE mark. In this process, the manufacturer submits the appropriate Quality Management System and Technical File documentation to the Notified Body for assessment. Upon successful certification/review, the Notified Body will issue EC certificate to the applicable annexes.

Table 1: Summary of Conformity Assessment Procedures to obtain a CE mark.

<table>
<tr><th rowspan="2">Classification</th><th rowspan="2">European Declaration of Conformity</th><th colspan="3">Conformity Assessment Evidence</th></tr>
<tr><th>European Regulation</th><th>QMS Certificate</th><th>Product Assessment</th></tr>
<tr><td>Class I</td><td>✓</td><td>N/A</td><td>N/A</td><td>N/A</td></tr>
<tr><td rowspan="6">Class Is</td><td rowspan="6">✓</td><td rowspan="4">EU MDD 93/42/EEC</td><td>Annex II.3</td><td rowspan="6">N/A</td></tr>
<tr><td>Annex IV (non-sterile where batches are included on certificate)</td></tr>
<tr><td>Annex V</td></tr>
<tr><td>Annex VI (non-sterile devices only)</td></tr>
<tr><td rowspan="2">EU MDR 2017/745</td><td>Annex IX (QMS) and III</td></tr>
<tr><td>Annex XI (Product Conformity Verification, Part A)</td></tr>
<tr><td rowspan="5">Class IIa</td><td rowspan="5">✓</td><td rowspan="3">EU MDD 93/42/EEC</td><td>Annex II.3</td><td rowspan="3">N/A</td></tr>
<tr><td>Annex IV (non-sterile where batches are included on certificate)</td></tr>
<tr><td>Annex V</td></tr>
<tr><td rowspan="2">EU MDR 2017/745</td><td>Annex IX, Chapter 1 (QMS) and III</td><td>Section 4, Annex IX (technical documentation)</td></tr>
<tr><td>Annexes II and III,</td><td>Section 10 or Section 18 of Annex XI (one representative device per category)</td></tr>
</table>

Classification	European Declaration of Conformity	Conformity Assessment Evidence		
		European Regulation	QMS Certificate	Product Assessment
Class IIb	✓	EU MDD 93/42/EEC	Annex II.3	N/A
			Annex IV (non-sterile, where specific batches are included on certificate), and Annex III	Annex III
			Annex V and Annex III	
			Annex VI (non-sterile devices only) and Annex III	
		EU MDR 2017/745	Annex IX, Chapter 1 (QMS) and III	Annex IX Section 4 (based on representative sample)
			Annex XI (Product Conformity Verification)	Annex X – Type Examination

Annex 1.4. Requirements for Review of Documentation (EU)

EU Declaration of Conformity

As per the requirements of the European Medical Devices Directive (MDD) and the European Medical Device Regulations 2017/745 (MDR), a valid EC or EU Declaration of Conformity[10] must be prepared and signed by the manufacturer.

The Declaration of Conformity should include the following elements:

- The manufacturer name and address.
- The name and address of the European Authorized Representative.
- A statement that the Declaration is issued under the responsibility of the manufacturer.
- Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the Declaration of Conformity.
- Details of the Notified Body who carried out the conformity assessment (if applicable).[11]
- Reference to the relevant legislation with which the product complies, including any harmonized standards.
- Name and signature of a representative of the manufacturer.
- Date the declaration was issued.

[10] https://ec.europa.eu/docsroom/documents/9781/attachments/1/translations
[11] Not required for Declarations of Conformity issued for Class I medical devices.

EU Conformity Assessment Certificate Requirements

A European Conformity Assessment certificate is issued by a Notified Body upon successful assessment of the conformity assessment evidence against the requirements of the applicable regulations (EU MDD or EU MDR). The EU conformity assessment certificates should contain at least the following information to confirm the validity of the certificate:

a) Name and identification number of the Notified Body.
b) Name and address of the manufacturer and the details of the authorized representative, (as applicable).
c) Scope (aligns with product being purchased).
d) Statement that the device/s comply with the applicable GSPR.
e) References of the standards or parts thereof where harmonized standards have been fully or partially applied.
f) Date of issue, date of expiry and, where appropriate, date(s) of renewal
g) Any conditions attached to the issue of the certificate.

The certificate details should also be cross-checked with the device-specific information, such as intended use, labelling and instructions for use.

EU Notified Body

It is good advice to verify the number, the competency and the validity of the designation of the Notified Body which is mentioned in the documentation and in particular to cross-check with the list of notified bodies which are designated to operate regarding the various directives using the following links:

- For Medical Device Directive: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13
- For Medical device Regulation: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

Annex 1.5. Summary of Requirements – Australia

Medical Device	Classification	AU Declaration of Conformity	QMS Certificate	Product Assessment	ARTG Certificate
Medical gas cylinder, portable	Class IIa	✓	✓	N/A	✓
Oxygen plant	Class IIa	✓	✓	N/A	✓
Airway (transient/short term use)	Class I	✓	N/A	N/A	✓
Airway (long term use)	Class IIa	✓	✓	N/A	✓
CO2 Detector (Colorimetric End Tidal)	Class I	✓	N/A	N/A	✓
Cricothyrotomy (transient or short term use)	Class IIa	✓	✓	N/A	✓
Endotracheal Tube (short term insertion)	Class IIa	✓	✓	N/A	✓
Endotracheal Tube (long term insertion)	Class IIb	✓	✓	✓	✓
Endotracheal Tube Introducer	Class I	✓	N/A	N/A	✓
Flow splitter	Class IIa	✓	✓	N/A	✓
Flowmeter, Medical O2, Gas Cylinder (administering to patient in conscious state)	Class IIa	✓	✓	N/A	✓
Flowmeter, Medical O2, Gas Cylinder (administering to patient in ICU)	Class IIb	✓	✓	✓	✓
Flowmeter, medical O2, Terminal (wall) Unit (administering to patient in conscious state)	Class IIa	✓	✓	N/A	✓
Flowmeter, medical O2, Terminal (wall) Unit (administering to patient in ICU)	Class IIb	✓	✓	✓	✓
Humidifier	Class IIa	✓	✓	N/A	✓
Infusion Giving Set	Class IIa	✓	✓	N/A	✓
Laryngoscope	Class I	✓	N/A	N/A	✓
Nasal Cannula (short term use)	Class I	✓	N/A	N/A	✓
Nasal Catheter (short term use)	Class I	✓	N/A	N/A	✓
Nasal Prong (short term use)	Class I	✓	N/A	N/A	✓
Oxygen mask	Class I	✓	N/A	N/A	✓
Pulse Oximeter Probes (monitoring patient in conscious state)	Class IIa	✓	✓	N/A	✓
Pulse Oximeter Probes (monitoring patient in ICU)	Class IIb	✓	✓	✓	✓
Resuscitator (not connected to active device)	Class I	✓	N/A	N/A	✓
Resuscitator (connected to active)	Class IIa	✓	✓	N/A	✓
Suction Device (for use on conscious patients)	Class IIa	✓	✓	N/A	✓

Medical Device	Classification	AU Declaration of Conformity	QMS Certificate	Product Assessment	ARTG Certificate
Suction Device (for use in hazardous situation e.g., ICU patient)	Class IIb	✓	✓	✓	✓
Tubing	Class IIa	✓	✓	N/A	✓
Mechanical Ventilation (administering to patients in conscious state)	Class IIa	✓	✓	N/A	✓
Mechanical Ventilation (administering to patients in ICU)	Class IIb	✓	✓	✓	✓
Non-Invasive Ventilation (administering to patients in conscious state)	Class IIa	✓	✓	N/A	✓
Non-Invasive Ventilation (administering to patients in ICU)	Class IIb	✓	✓	✓	✓
Oxygen Analyser (not directly administering to patient)	Class I	✓	N/A	N/A	✓
Oxygen Concentrator (administering to patients in conscious state)	Class IIa	✓	✓	N/A	✓
Oxygen Concentrator (administering to patients in ICU)	Class IIb	✓	✓	✓	✓
Pulse Oximeter Probes (monitoring patient in conscious state)	Class IIa	✓	✓	N/A	✓
Pulse Oximeter Probes (monitoring patient in ICU)	Class IIb	✓	✓	✓	✓
Surge suppressor	Not a medical device	N/A	N/A	N/A	N/A
Voltage stabilizer	Not a medical device	N/A	N/A	N/A	N/A
Blood Gas Analyser (monitoring patient in conscious state)	Class IIa	✓	✓	N/A	✓
Blood Gas Analyser (monitoring patient in ICU)	Class IIb	✓	✓	✓	✓
Electrocardiogram (ECG) digital monitor and recorder (monitoring patient in conscious state)	Class IIa	✓	✓	N/A	✓
Electrocardiogram (ECG) digital monitor and recorder (monitoring patient in ICU)	Class IIb	✓	✓	✓	✓
Electronic drop counter	Class IIa	✓	✓	N/A	✓
Infusion Pump	Class IIb	✓	✓	✓	✓
Patient monitor (monitoring patient in conscious state)	Class IIa	✓	✓	N/A	✓
Patient monitor (monitoring patient in ICU)	Class IIb	✓	✓	✓	✓
Thermometer	Class IIa	✓	✓	N/A	✓

Medical Device	Classification	AU Declaration of Conformity	QMS Certificate	Product Assessment	ARTG Certificate
Ultrasound (diagnosing/monitoring patient in conscious state)	Class IIa	✓	✓	N/A	✓
Ultrasound (diagnosing/(monitoring patient in ICU)	Class IIb	✓	✓	✓	✓
UPS Units	Not a medical device	N/A	N/A	N/A	N/A
X-ray: Equipment (administering radiation)	Class IIb	✓	✓	✓	✓

Annex 1.6. Evidence of Compliance – Australia

All medical devices within Australia require inclusion on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied within the Australian market. As evidence of inclusion, manufacturers are provided an ARTG certificate by the Australian regulator, the Therapeutics Goods Administration (TGA). This certificate provides the necessary evidence that the appropriate conformity assessment procedures have been applied for the class of device.

To obtain the ARTG certificate, the manufacturer submits the conformity assessment evidence (per Table 2) to the TGA for review. Availability of the required conformity assessment evidence provides assurance that the device should meet the requirements of the Australian regulations.

Class I Medical Devices

Like Europe, in Australia, Class I medical devices are exempt from premarket review by the TGA. However, devices must still be demonstrated to comply with the Essential Principles of Safety and Performance, following which the Legal Manufacturer prepares and signs a Declaration of Conformity[12] under the Australian Therapeutic Goods Regulations.

For Class I medical devices that are not intended to be supplied sterile and do not have a measuring function, the sponsor must submit the Declaration of Conformity with the medical device application for ARTG inclusion. Upon request by the TGA, the sponsors must also provide any other documentation relevant to the device including the device instructions for use, product labeling, advertising and evidence of performance.

[12] https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices

Class Is, Im, IIa and Class IIb Devices

For all other devices, medical device manufacturers are required to obtain evidence of conformity assessment of their device before applying for inclusion on the ARTG. Conformity Assessment may be conducted by the TGA, or alternatively the TGA also accepts evidence of overseas assessment[13] to support an application for inclusion on the ARTG. Class Is, Im, IIa and IIb medical devices are subject to a technical assessment generally based on higher level review of technical summary documents and spot checks at audit.

Table 2: Australian Conformity Assessment Evidence.

Classification	Australian Declaration of Conformity	Conformity Assessment Evidence	
		QMS Certificate	Product Assessment
Class I	✓	N/A	N/A
Class Is/Im/IIa	✓	Part 1 – Full Quality Assurance (Excl. Clause 1.6)	N/A
		Part 3 – Verification (non-sterile devices only)	
		Part 4 – Production Quality Assurance	
		Part 5 – Product Quality Assurance (non-sterile devices only)	
Class IIb	✓	Part 1 – Full Quality Assurance (Excl. Clause 1.6)	N/A
		Part 3 – Verification (non-sterile devices only)	Part 2 – Type Examination
		Part 4 – Production Quality Assurance	
		Part 5 – Product Quality Assurance (non-sterile devices only)	

Annex 1.7. Requirements for Review of Documentation – Australia

Australian Declaration of Conformity

The appropriate Declaration of Conformity template must be prepared based on the classification of the device and the conformity assessment procedures applied to the device as recommended by TGA.

For each of the conformity assessment procedures the Declaration of Conformity requirements have been specified in Schedule 3 of the Conformity Assessment procedures

[13] https://www.tga.gov.au/sites/default/files/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds.pdf

of the regulations. Templates detailing the requirements for the Australian Declaration of Conformity are available on the TGA's website.[14]

ARTG Certificate

An ARTG certificate provides evidence that the medical device has been included on the Australian Register of Therapeutic Goods, confirming that the device can be legally supplied in Australia for its intended purpose. The inclusion of the medical device on the ARTG also confirms that the conformity assessment evidence supporting the medical device has been assessed by the TGA and confirmed in compliance with the safety and performance requirements of the Therapeutic Goods Regulations. The publicly accessible version of the ARTG database[15] can be searched for all medical devices that can currently be supplied in Australia using:

- The product name.
- License details.
- Sponsor details.
  The ARTG number.

Annex 2. Canada

Annex 2.1. Summary of Requirements – Canada

✓: For manufacturers

△: For importers or distributors

Medical Device	Classification	Medical Device Establishment License	Medical Device License	MDSAP Certificate	Declaration of Conformity	Submission Document as per IMDRF guidance
Medical gas cylinder, portable	Class II	△	✓	✓	✓	✓
Oxygen plant (not a medical device)	Not Medical Device	N/A	N/A	N/A	N/A	N/A
Oxygen plant (administers oxygen directly to conscious and spontaneously breathing patient)	Class II	△	✓	✓	✓	✓

[14] TGA Declaration of conformity templates, 20 May 2021 https://www.tga.gov.au/form/declaration-conformity-templates-medicalhttps://www.tga.gov.au/form/declaration-conformity-templates-medical-devicesdevices

[15] Searching the Australian Register of Therapeutic Goods (ARTG): https://www.tga.gov.au/searching-australian-register-therapeutichttps://www.tga.gov.au/searching-australian-register-therapeutic-goods-artggoods-artg

Medical Device	Classification	Medical Device Establishment License	Medical Device License	MDSAP Certificate	Declaration of Conformity	Submission Document as per IMDRF guidance
Oxygen plant (administers oxygen directly to unconscious and non-spontaneously breathing patient in ICU)	Class III	△	✓	✓	✓	✓
Airway (only reaches as far as the pharynx)	Class I	✓ and △	N/A	N/A	N/A	N/A
Airway (reaches further than the pharynx)	Class II	△	✓	✓	✓	✓
Airway (remains in the body for at least 30 consecutive days	Class III	△	✓	✓	✓	✓
CO2 detector (failure to detect does not cause immediate danger to the patient)	Class II	△	✓	✓	✓	✓
CO2 detector (failure to detect could cause immediate danger to the patient e.g., in ICU)	Class III	△	✓	✓	✓	✓
Cricothyrotomy (if remains in body for less than 30 days)	Class II	△	✓	✓	✓	✓
Cricothyrotomy (If it remains in the body for at least 30 consecutive days)	Class III	△	✓	✓	✓	✓
Endotracheal tube (if remains in body for less than 30 days)	Class II	△	✓	✓	✓	✓
Endotracheal tube (If it remains in the body for at least 30 consecutive days)	Class III	△	✓	✓	✓	✓
Flow splitter	Class II	△	✓	✓	✓	✓
Flowmeter, medical O2, Gas Cylinder	Class II	△	✓	✓	✓	✓
Flowmeter, medical O2, Terminal (wall) Unit	Class II	△	✓	✓	✓	✓
Humidifier	Class II	△	✓	✓	✓	✓
Infusion giving set	Class II	△	✓	✓	✓	✓
Laryngoscope	Class II	△	✓	✓	✓	✓

Medical Device	Classification	Medical Device Establishment License	Medical Device License	MDSAP Certificate	Declaration of Conformity	Submission Document as per IMDRF guidance
Nasal Cannula	Class II	△	✓	✓	✓	✓
Nasal Catheter	Class II	△	✓	✓	✓	✓
Nasal prong	Class II	△	✓	✓	✓	✓
Oxygen mask	Class II	△	✓	✓	✓	✓
Pulse oximeter probes (failure to detect does not cause immediate danger to the patient)	Class II	△	✓	✓	✓	✓
Pulse oximeter probes (failure to detect could cause immediate danger to the patient e.g., in ICU)	Class III	△	✓	✓	✓	✓
Resuscitator	Class II	△	✓	✓	✓	✓
Suction Device (withdrawal not hazardous)	Class II	△	✓	✓	✓	✓
Suction Device (withdrawal is considered potentially hazardous)	Class III	△	✓	✓	✓	✓
Tubing (Oxygen Administration tubing)	Class II	△	✓	✓	✓	✓
Mechanical ventilation	Class III	△	✓	✓	✓	✓
Non-invasive ventilation	Class III	△	✓	✓	✓	✓
Oxygen analyser	Class I	✓ and △	N/A	N/A	N/A	N/A
Oxygen concentrator (for conscious and spontaneously breathing patients only)	Class II	△	✓	✓	✓	✓
Oxygen concentrator for unconscious or non-spontaneously breathing patients in ICU)	Class III	△	✓	✓	✓	✓
Pulse oximeter probes (failure to detect does not cause immediate danger to the patient)	Class II	△	✓	✓	✓	✓
Pulse oximeter probes (failure to detect could cause immediate danger to the patient e.g., in ICU)	Class III	△	✓	✓	✓	✓

Medical Device	Classification	Medical Device Establishment License	Medical Device License	MDSAP Certificate	Declaration of Conformity	Submission Document as per IMDRF guidance
Surge suppressor	Not a Medical Device	N/A	N/A	N/A	N/A	N/A
Voltage stabilizer	Not a Medical Device	N/A	N/A	N/A	N/A	N/A
Blood Gas Analyser (Blood Gas Analyser)	III IVDD	△	✓	✓	✓	✓
Blood Gas Analyser (Not life-threatening condition)	II IVD	△	✓	✓	✓	✓
Blood Gas Analyser (Life-threatening condition)	III IVD	△	✓	✓	✓	✓
Electrocardiogram (ECG) digital monitor and recorder (failure to detect does not cause immediate danger to the patient)	Class II	△	✓	✓	✓	✓
Electrocardiogram (ECG) digital monitor and recorder (failure to detect could cause immediate danger to the patient)	Class III	△	✓	✓	✓	✓
Electronic drop counter	Class II	△	✓	✓	✓	✓
Infusion pump	Class III	△	✓	✓	✓	✓
Patient monitor (failure to detect does not cause immediate danger to the patient)	Class II	△	✓	✓	✓	✓
Patient monitor (failure to detect could cause immediate danger to the patient)	Class III	△	✓	✓	✓	✓
Thermometer	Class II	△	✓	✓	✓	✓
Ultrasound	Class III	△	✓	✓	✓	✓
UPS units	Not a Medical Device	N/A	N/A	N/A	N/A	N/A
X-ray: Equipment (used in radiographic mode)	Class II	△	✓	✓	✓	✓
X-ray: Equipment (used other than radiographic mode)	Class III	△	✓	✓	✓	✓

Medical Device	Classification	Medical Device Establishment License	Medical Device License	MDSAP Certificate	Declaration of Conformity	Submission Document as per IMDRF guidance
Radiographic film view box, non-powered	Class I	✓ and △	N/A	N/A	N/A	N/A

Annex 2.2. Medical Device Classification and Reference for Canada

Medical Device	Classification	Guidance	Reference[16]
Medical gas cylinder, portable	Class II	N/A	Rule 5
Oxygen plant	Not Medical Device	If not administering oxygen directly to the patients but through an intermediary vessel.	N/A
	Class II	If it administers oxygen directly to the patient and if used for conscious and spontaneously breathing patients only, where failure to deliver the appropriate dosage characteristics is not potentially hazardous.	Rule 11(1)
	Class III	If it administers oxygen directly to the patient and if used for unconscious or non-spontaneously breathing patients in intensive-care units	Rule 11(2)
Airway	Class I	If it only reaches as far as the pharynx	Rule 2(2)
	Class II	If it reaches further than the pharynx	Rule 2(1)
	Class III	If it remains in the body for at least 30 consecutive days	Rule 2(3)
CO2 detector	Class II	If failure to detect an abnormal physical state (such as erroneous readings) does not cause immediate danger to the patient	Rule 10(1)
	Class III	If failure to detect an abnormal physical state (such as erroneous readings) could cause immediate danger to the patient	Rule 10(2)
Cricothyrotomy	Class II	N/A	Rule 1(1)
	Class III	If it remains in the body for at least 30 consecutive days	Rule 1(3)
Endotracheal tube	Class II	N/A	Rule 2 (1)
	Class III	If it remains in the body for at least 30 consecutive days	Rule 2 (3)

[16] Schedule 1 (Section 6) of Medical Device Regulations (SOR98-282). Only the rule(s) that gives the highest risk class is listed when multiple rules apply.

Medical Device	Classification	Guidance	Reference[16]
Flow splitter	Class II	N/A	Rule 5 / Rule 7(2)(b)
Flowmeter, medical O2, Gas Cylinder	Class II	N/A	Rule 5 / Rule 7(2)(b)
Flowmeter, medical O2, Terminal (wall) Unit	Class II	N/A	Rule 5 / Rule 7(2)(b)
Humidifier	Class II	N/A	Rule 9(1)
Infusion giving set	Class II	N/A	Rule 5 / Rule 1(1)
Laryngoscope	Class II	N/A	Rule 1 (1)
Nasal Cannula	Class II	N/A	Rule 5 / Rule 7(2)(b)
Nasal Catheter	Class II	N/A	Rule 5 / Rule 7(2)(b)
Nasal prong	Class II	N/A	Rule 5 / Rule 7(2)(b)
Oxygen mask	Class II	N/A	Rule 5 / Rule 7(2)(b)
Pulse oximeter probes	Class II	If failure to detect an abnormal physical state (such as erroneous readings) does not cause immediate danger to the patient	Rule 10(1)
	Class III	If failure to detect an abnormal physical state (such as erroneous readings) could cause immediate danger to the patient	Rule 10(2)
Resuscitator	Class II	N/A	Rule 5
Suction Device	Class II	N/A	Rule 11 (1)
	Class III	If the withdrawal is considered potentially hazardous	Rule 11 (2)
Tubing	Class II	Oxygen Administration tubing	Rule 5 / 7(2)(b)
Mechanical ventilation	Class III	N/A	Rule 11 (2)
Non-invasive ventilation	Class III	N/A	Rule 11 (2)
Oxygen analyser	Class I	N/A	Rule 12
Oxygen concentrator	Class II	If used for conscious and spontaneously breathing patients only, where failure to deliver the appropriate dosage characteristics is not potentially hazardous.	Rule 11 (1)
	Class III	If used for unconscious or non-spontaneously breathing patients in intensive-care units	Rule 11 (2)
Pulse oximeter	Class II	If failure to detect an abnormal physical state does not cause immediate danger to the patient	Rule 10(1)
	Class III	If failure to detect an abnormal physical state could cause immediate danger to the patient	Rule 10(2)
Surge suppressor	Not Medical Device		N/A
Voltage stabilizer	Not Medical Device		N/A

Medical Device	Classification	Guidance	Reference[16]
Blood Gas Analyser	III IVDD	Near-patient device (home use or point-of care)	IVDD Rule 6
	II IVD	Not life-threatening condition	IVDD Rule 3/4
	III IVD	Life-threatening condition	IVDD Rule 3/4
Electrocardiogram (ECG) digital monitor and recorder	Class II	If failure to detect an abnormal physical state does not cause immediate danger to the patient	Rule 10(1)
	Class III	If failure to detect an abnormal physical state could cause immediate danger to the patient	Rule 10(2)
Electronic drop counter	Class II	N/A	Rule 11
Infusion pump	Class III	N/A	Rule 11 (2)
Patient monitor	Class II	If failure to detect an abnormal physical state (such as erroneous readings) does not cause immediate danger to the patient	Rule 10(1)
	Class III	If failure to detect an abnormal physical state (such as erroneous readings) could cause immediate danger to the patient	Rule 10(2)
Thermometer	Class II	N/A	Rule 10(1)
Ultrasound	Class III	N/A	Rule 10(2)
UPS units	Not a Medical Device		N/A
X-ray: Equipment	Class II	Intended to be used in radiographic mode	Rule 8(2)
	Class III	Intended use other than radiographic mode.	Rule 8(1)
Radiographic film view box, non-powered	Class I	N/A	Rule 7(1) / Rule 12

Annex 2.3. Evidence of Compliance

Classification	Risk	1. Medical Device Establishment License	2. Medical Device License	3. MDSAP Certificate	4. Declaration of Conformity	5. Submission Document as per IMDRF guidance
Class I	Low	✓ and △	N/A	N/A	N/A	N/A
Class II	Low-Moderate	△	✓	✓	✓	✓
Class III	Moderate-High	△	✓	✓	✓	✓
Class IV	High	△	✓	✓	✓	✓

✓ : for manufacturers

△:For importers or distributors

Annex 2.4. Requirements for Review of Documentation – Canada

Medical Device Establishment License (MDEL)

- An MDEL is issued to Class I manufacturers as well as importers or distributors of **all** device classes to permit them to import or distribute a medical device in Canada.
- It provides Health Canada assurance that medical devices sold or imported into Canada meet the safety requirements set out in the Canadian Medical Devices Regulations (CMDR), and those procedures are in place to protect the public should a problem with a device be identified.
- The MDEL listing should contain information about the licensed establishment including their company ID, license number, company name, address, authorized activities and associated class of device(s).

Medical Device License

- A manufacturer must obtain a Medical Device License (MDL) issued by Health Canada before importing, advertising, or selling any Class II, III, or IV device in Canada.
- The MDL should contain information about license number, issue date, device class, device name, license type (e.g., single device or system), manufacturer name and address and a list of components/parts/accessories/devices covered by the license (if applicable).

MDSAP Certificate

Manufacturers must hold a Medical Device Single Audit Program (MDSAP) certificate as evidence of the compliance of its quality management system with ISO 13485:2016 as well as the specific requirements of the Canadian Medical Device Regulations (CMDR).

Declaration of Conformity

The Canadian Declaration of Conformity (DoC) should include the following information:

- Information of the manufacturer.
- Standard(s) as stated on the TPD Recognized Standards List (including indications of any inapplicable requirements of the Recognized Standards and any deviations).
- Information of Testing Laboratory or Certification Body which was used to determine the conformance of the medical device with the Recognized Standards.
- A statement that the declaration is issued under a senior official of the manufacturer, including date of issue of the declaration, identification and signature of the manufacturer.

Submission document as per IMDRF guidance

- Manufacturers who have obtained MDLs for class II, III or IV devices should also have submission documentation in file in a format according to the Table of Contents (ToC) developed by the International Medical Device Regulators Forum (IMDRF).

Annex 3. United States

Annex 3.1. Summary of Requirements – United States

Medical Device	Classification	General Controls and 510(k) exempt /GUDID listing	510(k) Clearance
Medical gas cylinder, portable	Not a Medical Device	N/A	N/A
Oxygen plant (not be used for or with any life-supporting applications.)	Class II	N/A	✓
Airway	Class I	✓	N/A
CO2 detector	Class II	N/A	✓
Cricothyrotomy	Class II	N/A	✓
Endotracheal tube	Class II	N/A	✓
Flow splitter	Class I	✓	N/A
Flowmeter, medical O2, Gas Cylinder	Class I	✓	N/A
Flowmeter, medical O2, Terminal (wall) Unit	Class I	✓	N/A
Humidifier	Class I	✓	N/A
Infusion giving set	Class II	N/A	✓
Laryngoscope	Class I	✓	N/A
Nasal Cannula	Class I	✓	N/A
Nasal Catheter	Class I	✓	N/A
Nasal prong	Class I	✓	N/A
Oxygen mask	Class I	✓	N/A
Pulse oximeter probes	Class II	N/A	✓
Resuscitator	Class II	N/A	✓
Suction device	Class II	✓	N/A
Tubing (used as a conduit for gases between a ventilator and a patient during ventilation of the patient)	Class I	✓	N/A
Tubing (suction tubing)	Class II	✓	N/A
Mechanical ventilation	Class II	N/A	✓
Non-invasive ventilation (noncontinuous ventilator to assist a patient's breathing)	Class II	N/A	✓
Non-invasive ventilation (device attached to a ventilator that is used to elevate pressure in a patient's lungs	Class I	✓	N/A

Medical Device	Classification	General Controls and 510(k) exempt /GUDID listing	510(k) Clearance
above atmospheric pressure at the end of exhalation)			
Oxygen analyser	Class II	N/A	✓
Oxygen concentrator	Class II	N/A	✓
Pulse oximeter	Class II	N/A	✓
Surge suppressor	The device by itself is not considered as a medical device in the US	N/A	N/A
Voltage stabilizer	The device by itself is not considered as a medical device in the US	N/A	N/A
Blood Gas Analyser	Class II	N/A	✓
Electrocardiogram (ECG) digital monitor and recorder	Class II	N/A	✓
Electronic drop counter	Class II	N/A	✓
Infusion pump	Class II	N/A	✓
Patient monitor	Class II	N/A	✓
Thermometer	Class II	N/A	✓
Ultrasound	Class II	N/A	✓
X-ray: Equipment	Class II	N/A	✓

Annex 3.2. Medical Device Classification and Reference for United States

Medical Device	Classification	Guidance	Product Code	CFR No.	Regulatory Pathway
Medical gas cylinder, portable	Class I	Classification assumes that the cylinder incorporates a pressure regulator.	ECX, CAN	868.2700	Class I (General Control)
Oxygen plant	Class II	The device must not be used for or with any life-supporting applications.	CAW	868.5440	510(k)
Airway	Class I	N/A	BTQ	865.5100	Class I (General Control)
			CAE	868.5110	
CO2 detector	Class II	N/A	CCK	868.1400	510(k)
Cricothyrotomy	Class II	N/A	BWC, JOH, OGP	868.5090	510(k)

Medical Device	Classification	Guidance	Product Code	CFR No.	Regulatory Pathway
Endotracheal tube	Class II	N/A	BTR	868.5730	510(k)
			BSK	868.5750	
Flow splitter	Class I	N/A	BYM, CAX	868.5860/868.2340	Class I (General Control)
Flowmeter, medical O2, Gas Cylinder	Class I	N/A	ECX, CAN	868.2700	Class I (General Control)
Flowmeter, medical O2, Terminal (wall) Unit	Class I	N/A	BXY	868.2350	Class I (General Control)
Humidifier	Class I	N/A	KFZ	868.5460	Class I (General Control)
Infusion giving set	Class II	N/A	LHI, FPK	880.5440	510(k)
Laryngoscope	Class I	N/A	CCW	868.554	Class I (General Control)
Nasal Cannula	Class I	N/A	CAT	868.5340	Class I (General Control)
Nasal Catheter	Class I	N/A	BZB	868.5350	Class I (General Control)
Nasal prong	Class I	N/A	CAT	868.5340	Class I (General Control)
Oxygen mask	Class I	N/A	BYG	868.5580	Class I (General Control)
			BYF	868.5600	
Pulse oximeter probes	Class II	N/A	DQA	870.2700	510(k)
Resuscitator	Class II	N/A	BTM	868.5915	510(k)
			BTL	868.5925	
Suction device	Class II	N/A	GCX JOL	880.6740	510(k) Exempt
Tubing	Class I	A device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.	BZO BYX	868.5975 868.5860	Class I (General Control)

Medical Device	Classification	Guidance	Product Code	CFR No.	Regulatory Pathway
	Class II	Suction Tubing	GAZ	880.6740	510(k) Exempt
Mechanical ventilation	Class III	High Frequency Ventilation	LSZ	868.5895	PMA
	Class II	N/A	ONZ, BTM	868.5895 868.5915	510(k)
Non-invasive ventilation	Class II	A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing	MNT	868.5895	510(k)
	Class I	A device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.	BYE	868.5965	Class I (General Control)
Oxygen analyser	Class II	N/A	CCL	868.1720	510(k)
Oxygen concentrator	Class II	N/A	CAW	868.5440	510(k)
Pulse oximeter	Class II	N/A	DQA	870.2700	510(k)
Surge suppressor	The device by itself is not considered as a medical device in the US		N/A	N/A	N/A
Voltage stabilizer	The device by itself is not considered as a medical device in the US		N/A	N/A	N/A
Blood Gas Analyser	Class II	N/A	CHL	862.1120	510(k)
Electrocardiogram (ECG) digital monitor and recorder	Class II	N/A	MWJ	870.2800	510(k)
Electronic drop counter	Class II	N/A	FLN	880.2420	510(k)
Infusion pump	Class II	N/A	FRN	880.5725	510(k)
Patient monitor	Class II	N/A	MHX	870.1025	510(k)
Thermometer	Class II	N/A	FLL	880.2910	510(k)
Ultrasound	Class II	N/A	IYN	892.1550	510(k)
X-ray: Equipment	Class II	N/A	N/A	892.1680	510(k)

Annex 3.3. Evidence of Compliance – United States

Low Risk (Class I) Devices – General Controls

Class I devices are exempt from premarket review by the FDA (Food and Drugs Administration), although they must still conform to the safety and effectiveness requirements specified in the regulations. Most of these devices are also subject to General Controls (e.g., labelling requirements), attract establishment and device listing requirements i.e., listing on FDA's Unified Registration and Listing System (FURLS).

Medium Risk (Class II) Devices – 510(k) Exempt

Some medium risk devices (Class II) that have existing or reasonably foreseeable characteristics of commercially distributed devices are exempt from pre-market notification procedure (i.e., 510(k) submission) under section 880.9 of the US regulations. However, these devices are still subject to General Controls (e.g., labelling requirements) and attract establishment and device listing requirements (i.e., listing on FURLS).

Medium Risk (Class II) Devices – 510(k)

Class II devices are in most cases subject to "premarket notification" and FDA clearance under the 510(k) program. These submissions include a summary of technical design data and verification/validation reports primarily intended to establish safety and substantial equivalence in terms of use, design and technology to a predicate device (i.e., a similar device which is already legally supplied in the USA). The product technical requirements set forth by FDA are called special controls. These are defined in the regulation in place for the device type. Typically, these include requirements for compliance with specific product standards or FDA guidance documents.

Annex 3.4. Requirements for Review of Documentation – United States

General Controls and 510(k) Exempt

The market clearance of the device in the US can be verified by visiting the "Access GUDID"[17] website and searching the devices by their names, UDI, or company name. The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

[17] https://accessgudid.nlm.nih.gov/

Figure 1: Global Unique Device Identification Database

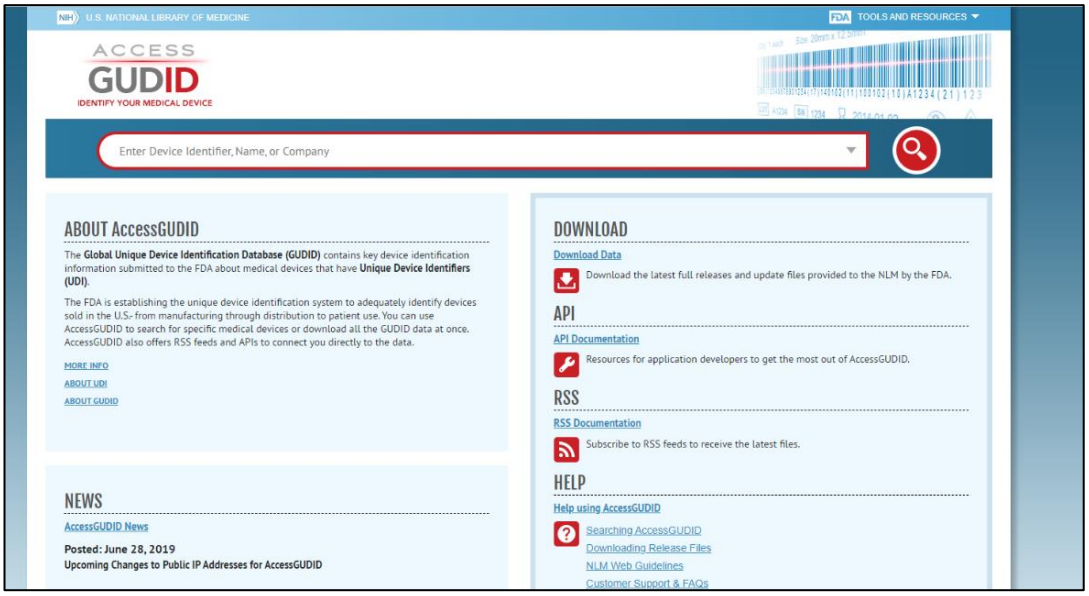
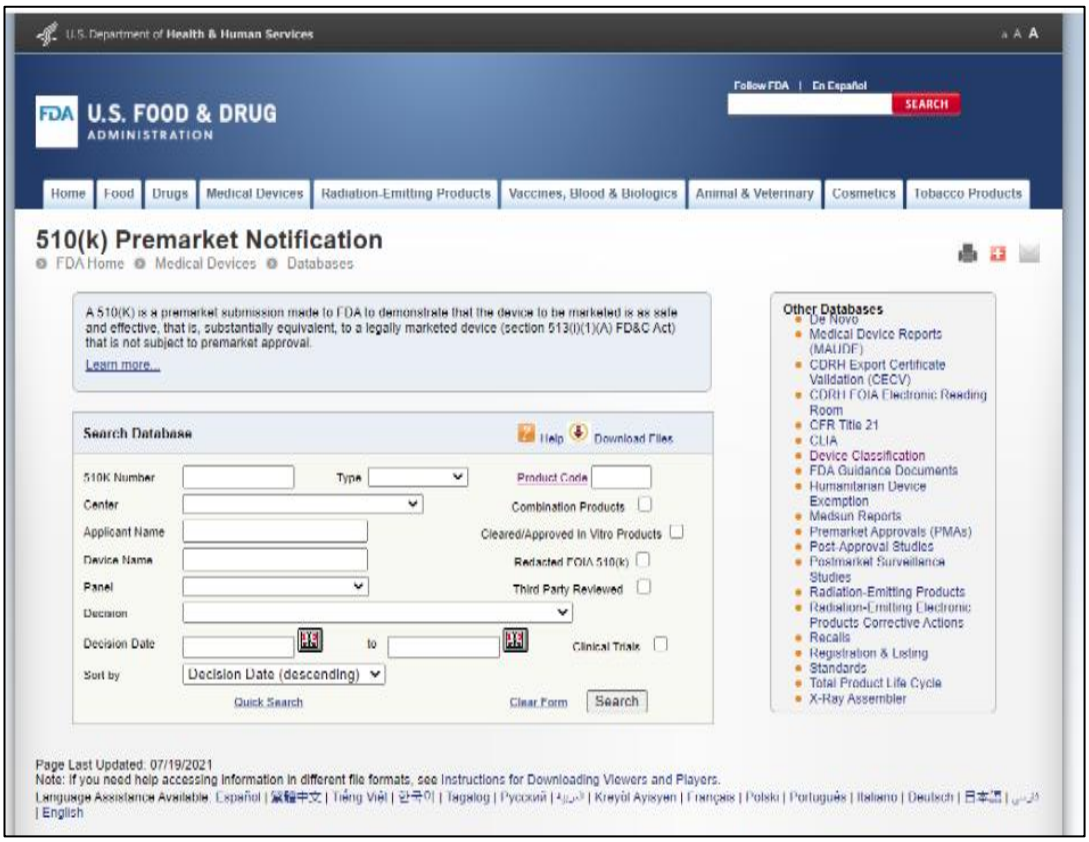


Figure 2: FDA 510(K) Pre-Market Notification Website



Annex 4. Japan

The classification and regulatory system in Japan differ from the other jurisdictions included in this Briefing Note. In Japan, the classification of a medical device is determined by the Classification Catalogue where the authority assigns each device one of the Japanese Medical Device Nomenclature (JMDN) codes and its corresponding risk class.

The regulatory pathway is partially based on the risk class but also dependent on whether a Japanese Industrial Standard (JIS) is available for the product. For example, if an X-ray device is used for imaging of the lung, it will be categorized into a "lung X-ray device"; if it is for mammography, it will be categorized into "mammography X-ray device". If it is used for both intended purposes, both JMDNs are selected, and the more rigorous assessment pathway will be followed.

Annex 4.1. Summary of Requirements

Medical Device	Classification	Pre- market Notification/Application form	Pre-market Certification	Pre-market Approval	RCB Review	PMDA Review	Tech file in STED
Medical gas cylinder, portable	Not a medical device	N/A	N/A	N/A	N/A	N/A	N/A
Oxygen plant	Class II	✓	N/A	✓	N/A	✓	✓
	Class III	✓	N/A	✓	N/A	✓	✓
Airway	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
CO2 detector	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
Cricothyrotomy	Class II	✓	✓	N/A	✓	N/A	✓
Endotracheal tube	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
	Class III	✓	N/A	✓	N/A	✓	✓
Flow splitter	Class III	✓	N/A	✓	N/A	✓	✓
Flowmeter, medical O2, Gas Cylinder	Class II	✓	✓	N/A	✓	N/A	✓
Flowmeter, medical O2, Terminal (wall) Unit	Class III	✓	N/A	✓	N/A	✓	✓

Medical Device	Classification	Pre- market Notification/Application form	Pre-market Certification	Pre-market Approval	RCB Review	PMDA Review	Tech file in STED
Humidifier	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
Infusion giving set	Class II	✓	N/A	✓	N/A	✓	✓
Laryngoscope	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
Nasal Cannula	Class II	✓	✓	N/A	✓	N/A	✓
Nasal Catheter	Class II	✓	✓	N/A	✓	N/A	✓
Nasal prong	Class II	✓	✓	N/A	✓	N/A	✓
Oxygen mask	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
Pulse oximeter probes	Class I	✓	N/A	N/A	N/A	N/A	N/A
Resuscitator	Class III	✓	N/A	✓	N/A	✓	✓
Suction device	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
Tubing	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
Mechanical ventilation	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
	Class III	✓	✓	N/A	✓	N/A	✓
	Class III	✓	N/A	✓	N/A	✓	✓
Non-invasive ventilation	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
	Class III	✓	✓	N/A	✓	N/A	✓
	Class III	✓	N/A	✓	N/A	✓	✓
Oxygen analyser	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
Oxygen concentrator	Class II	✓	✓	N/A	✓	N/A	✓
	Class III	✓	N/A	✓	N/A	✓	✓
Pulse oximeter	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓

Medical Device	Classification	Pre- market Notification/Application form	Pre-market Certification	Pre-market Approval	RCB Review	PMDA Review	Tech file in STED
Surge suppressor	Not a medical device	N/A	N/A	N/A	N/A	N/A	N/A
Voltage stabilizer	Not a medical device	N/A	N/A	N/A	N/A	N/A	N/A
Blood Gas Analyser	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
Electrocardiogram (ECG) digital monitor and recorder	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
	Class III	✓	✓	N/A	✓	N/A	✓
	Class III	✓	N/A	✓	N/A	✓	✓
	Class IV	✓	N/A	✓	N/A	✓	✓
Electronic drop counter	Class II	✓	N/A	✓	N/A	✓	✓
	Class III	✓	N/A	✓	N/A	✓	✓
Infusion pump	Class II	✓	✓	N/A	✓	N/A	✓
	Class III	✓	N/A	✓	N/A	✓	✓
	Class IV	✓	N/A	✓	N/A	✓	✓
Patient monitor	Class II	✓	✓	N/A	✓	N/A	✓
	Class II	✓	N/A	✓	N/A	✓	✓
Thermometer	Class II	✓	✓	N/A	✓	N/A	✓
Ultrasound	Class II	✓	✓	N/A	✓	N/A	✓
UPS units	Not a medical device	N/A	N/A	N/A	N/A	N/A	N/A
X-ray: Equipment	Class I	✓	N/A	N/A	N/A	N/A	N/A
	Class II/III	✓	✓	N/A	✓	N/A	✓
	Class II/III	✓	N/A	✓	N/A	✓	✓

Annex 4.2. Medical Device Classification and Reference for Japan

Medical Device	Classification*	JMDN code	Regulatory Pathway
Medical gas cylinder, portable	N/A	Not a medical device	N/A

Medical Device	Classification*	JMDN code	Regulatory Pathway
Oxygen plant	Class II	70581000	Shonin
	Class III	37230000	Shonin
Airway	Class II	35203000 36306000	Ninsho
	Class II	36231000	Shonin
CO2 detector	Class I	17477000 35617000	Todokede
	Class II	17148050 17148020 37061000 37178000	Ninsho
Cricothyrotomy	Class II	15028000	Ninsho
Endotracheal tube	Class I	36131000 42075000 41829000 37469000 31327000 31264000	Todokede
	Class II	42424012 42422000 42424022 70250002 17935002 36064002 14085012 31329000 14085042 70254000 32202000 14085022	Ninsho
	Class II	14082012 70257000 14082022	Shonin
	Class III	17935003 36064003 14085003 14082003 42424003 70250003 42421000 46877003	Shonin
Flow splitter	Class III	12873003	Shonin
Flowmeter, medical O2, Gas Cylinder	Class II	37132000	Ninsho
Flowmeter, medical O2, Terminal (wall) Unit	Class III	37498000	Shonin
Humidifier	Class I	35113000	Todokede
	Class II	70562000	Ninsho
Infusion giving set	Class II	17825000	Shonin
Laryngoscope	Class I	70948009 70947000	Todokede
	Class II	36645000 36706010 15076000 36706020 70123020 35462000 70123010	Ninsho
Nasal Cannula	Class II	35203000 35202000	Ninsho
Nasal Catheter	Class II	36306000	Ninsho
Nasal prong	Class II	35201000	Ninsho
Oxygen mask	Class II	35171000 35175000 36066000 35173000	Ninsho
	Class II	36231000	Shonin
Pulse oximeter probes	Class I	37808000 31658000	Todokede
Resuscitator	Class III	13366000 70594000 17141000 17591000 35308000 57981003 36086000 35309000	Shonin

Medical Device	Classification*	JMDN code	Regulatory Pathway
Suction device	Class II	41643000	Ninsho
	Class II	33579000	Shonin
Tubing	Class II	32202000 14085042 35203000	Ninsho
	Class II	36231000	Shonin
Mechanical ventilation	Class I	36277000	Todokede
	Class II	16803000 37705000	Ninsho
	Class II	70081000 42909000	Shonin
	Class III	17591000	Ninsho
	Class III	13366000 17877000 36289000 36943000 17141000 15783000 17865000 14361000 37038000 42411000 70561000	Shonin
Non-invasive ventilation	Class II	70579000 70583000 70569000 70577000 35202000	Ninsho
	Class II	70582000	Shonin
	Class III	36700000 37234000	Ninsho
	Class III	36990000 12061000 37230000 37498000 35115000	Shonin
Oxygen analyser	Class I	12590000 35219000	Todokede
	Class II	70085000	Ninsho
Oxygen concentrator	Class II	12873002	Ninsho
	Class III	12873003	Shonin
Pulse oximeter	Class II	17148020 17148010	Ninsho
	Class II	36118000	Shonin
Surge suppressor	N/A	Not a Medical Device	N/A
Voltage stabilizer	N/A	Not a Medical Device	N/A
Blood Gas Analyser	Class I	12590000 35219000 30847000	Todokede
	Class II	36346000	Ninsho
	Class II	37199000	Shonin
Electrocardiogram (ECG) digital monitor and recorder	Class I	35562010 17460000	Todokede
	Class II	31733000 36365000 36367000 32547000 14345000 70063000 36872000 70045000 70066000 35195000 70064000 11407020 33586002 11407030 35162000 11407010	Ninsho
	Class II	70062000 34115000 34972000 36719000 13085000 43958000	Shonin
	Class III	36548000	Ninsho

Medical Device	Classification*	JMDN code	Regulatory Pathway
	Class III	48051003 17579000	Shonin
	Class IV	37265000 46359004	Shonin
Electronic drop counter	Class II	36244000	Shonin
	Class III	11010000 12504003	Shonin
Infusion pump	Class II	5932000 13209000 13217000 13215000	Ninsho
	Class III	16167000 35983000 17634000 17907010 34071000	Shonin
	Class IV	35687000	Shonin
Patient monitor	Class II	31733000 32547000 14345000 70063000 36872000 70066000 36548000 35195000 11407020 33586002 11407030 35162000 11407010	Ninsho
	Class II	70062000 34115000 13085000 43958000	Shonin
Thermometer	Class II	17887000	Ninsho
Ultrasound	Class II	40761000 17888000	Ninsho
UPS units	N/A	Not a Medical Device	N/A
X-ray: Equipment	Class I	41011000 35839000 41012000	Todokede
	Class II/III	More than a hundred; more detailed information is needed.	Ninsho/Shonin

Annex 4.3. Evidence of Compliance for Japan

Regulatory Pathway	Assessment Agency	Compliance Evidence
1. Todokede	PMDA	Pre-market Notification
2. Ninsho	Registered Certification Body (RCB)	Pre-market Certification
3. Shonin	PMDA/MHLW	Pre-market Approval

Annex 4.4. Requirements for Review of Documentation – Japan

Todokede (Seizouhanbai-Todoke)

- All Class I devices marketed in Japan must have a pre-market notification filing with the Pharmaceuticals and Medical Devices Agency (PMDA). This is a notification only, and therefore no review/assessment by the PMDA is conducted.

- The notification form includes the following elements:

- Intended use.
- Description-Shape, Structure, Principles of operation.
- Raw materials.
- Specification of Performance and Safety.
- How to use.
- Storage method and shelf life.
- Manufacturing process.
- Manufacturing sites.
- Instruction for Use (IFU).
- Overview photo.

Ninsho (Seizouhanbai-Ninsho)

- Class II and a limited number of Class III devices which have an associated Japan Industrial Standard (JIS), are subject to pre-market certification. The process is similar to the European CE marking process where assessments are conducted by to a third party similar to a Notified Body- In Japan, reviews are outsourced to a Registered Certification Body (RCB).

- Manufacturers who obtained a Ninsho certification should have the following submission documentation in file:
  - Application Form (content is the same as the Notification Form for Class I devices).
  - Technical Files prepared in the STED format as developed by the Global Harmonization Task Force (GHTF/SG1/N063:2011).
  - The raw testing data associated with the above technical files.

Shonin (Seizouhanbai-Shonin)

- Class II and Class III devices without a specific JIS are subject to the pre-market approval process. This pathway also applies to all Class IV devices. In this case, a pre-market approval application is required to be filed with the PMDA and ultimately be approved by the Ministry of Health, Labour and Welfare (MHLW).
- Manufacturers who obtained a Shonin approval should have the following submission documentation on file (same for Ninsho pathway):
  - Application Form (content is the same as the Notification Form for Class I devices).
  - Technical Files prepared in the STED format as developed by the Global Harmonization Task Force (GHTF/SG1/N063:2011).
  - The raw testing data associated with the above technical files.

Annex 5: List of Emergency Procedures as per the Global Fund Interim Guidance

Europe

The European Commission has published specific guidelines regarding the commission's response to the COVID-19 pandemic. A summary is provided here, which includes the links to the specific applicable guidance: https://ec.europa.eu/docsroom/documents/41385/attachments/1/translations/

Australia

There are currently no emergency provisions related to COVID-19. Any change in this regard will be posted on the TGA website: https://www.tga.gov.au/safety-information/covid-19

Canada

Health Canada has published the "Interim Order No. 2 Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19" which relates to the import/supply of medical devices which are needed for support of the COVID-19 response, and may/may not fully meet regulatory requirements:
https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drug-medical-device-food-shortages/interim-order-2021.html

US FDA

The FDA has details and a list of products that have been approved under Emergency Use Authorization in response to the COVID-19 pandemic:

https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices