Title: Registration Provision Procedure	**Document No.:** YGD 0405
Effective: 30/03/2023	**Revision:** 3
Revised By: Shangari	**Approved By:** Punitha

1.0 OBJECTIVE

To facilitate the registration of medical device in United States (US), Australia, Brazil, Canada, Japan and other countries by providing required regulations of each individual country.
To ensure that this procedure is followed to meet all regulatory requirements for registration of medical device in United States (US), Australia, Brazil, Canada, Japan and other countries.

2.0 SCOPE

This procedure shall cover the general regulatory requirements for registration of medical device in specific markets with special references and inclusions of guidelines stated herein.

3.0 REFERENCE

i) US FDA 21CFR Food and Drugs. Chapter 1 -- Food and drug administration department of health and human services. Subchapter H – Medical devices. Part 807 -- Establishment registration and device listing for manufacturers and initial importers of devices.
ii) YGD 0303 -- Procedure for 510K format and for Deciding When to Submit A 510 (K).
iii) Canadian Medical Devices Regulations (CMDR) SOR/98-282.
iv) Health Canada.
v) Medical Device Single Audit Program (MDSAP).
vi) ISO 13485: 2016.
vii) Australian Regulatory Guideline for Medical Devices (ARGMD).
viii) Therapeutic Goods Act 1989 (The Act).
ix) The Therapeutic Goods [Medical Devices] Regulations 2002 (The Regulation).
x) Brazilian Resolution RDC 185/2001, ANVISA.
xi) Brazilian Regulation RDC 81/2008, ANVISA.
xii) Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013).
xiii) Brazilian Resolution 36/2015, ANVISA.
xiv) Brazilian Resolution RDC 102/2016, ANVISA.
xv) Ministry of Health, Labor, and Welfare (MHLW) Ordinance No.169.
xvi) Pharmaceutical & Medical Devices Act (PMDA).
xvii) Chinese Guobiao (GB) standard.
xviii) Egyptian Central Administration of Pharmaceutical Affairs (CAPA).
xix) French Agency for the Safety of Health Products (ANSM).
xx) Malaysian Medical Device Authority (MDA).
xxi) MEDSAFE (the New Zealand Medicines and Medical Devices Safety Authority).
xxii) Philippian Bureau of Food and Drugs (BFAD).
xxiii) Russian Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor).
xxiv) Singaporean Health Sciences Authority (HAS).
xxv) Vietnamese Department of Medical Equipment and Health Works (DMEHW).
xxvi) Indian Central Drug Standards Control Organization (CDSCO).
xxvii) Korean Ministry of Food and Drug Safety (MFDS).
xxviii) Turkish Medicines and Medical Devices Agency (TMMDA).
xxix) The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte or BfArM).

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4.0 DEFINITION

Medical device registration process is simplified steps as outlined below, to be taken in order to obtain the approval of one of these recognized markets (Australian, Brazilian, Canadian and Japanese). This procedure includes a different registration procedure in US market. In US, registration includes "New facility" of those establishments (also known as facility) that are involved in the production and distribution of medical devices; and "510(k) submission" to register the medical device.

5.0 RESPONSIBILITY

5.1 It is the responsibility of the Head of Regulatory Affairs to follow this procedure for registration of medical device/facility or to submit any changes to the devices that may require new submission or documentation of the changes.

5.2 It is the responsibility of the Department Heads and Executives to understand the procedures in order to maintain the registration information of the devices in aspects of manufacturing processes and other activities in the production and distribution of the device.

5.3 It is the responsibility of the RA Executive to follow-up with the Head of Regulatory Affairs on the feedbacks from authorities of United States (US), Australia, Brazil, Canada, Japan and other countries, within the timeline.

6.0 PROCEDURE

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6.1 REGISTRATION PROCEDURE IN UNITED STATES (US):

A. Establishment registration and device listing for manufacturers and initial importers of devices:

1) Establishment that is not located in US, engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into US shall register such establishment and list such devices using the FDA electronic device registration and listing system in conformance with the procedures explained below. The official correspondent for the foreign establishment shall facilitate the communication between foreign establishment and representatives of FDA for any matter relating registration of device establishment and the listing of device products.

2) Upon initial registration, annually or at the time of changes, foreign establishment shall register and list by using FDA electronic device registration and listing system. For registration of the establishment, the owner or operator required to submit the name, address, phone and fax numbers, email address, registration number (if has been assigned), all mentioned information of each individual importers or those offer to import in the US. The importer can be agent, broker, or other parties.

3) The US agent shall reside or maintain a place of business in the US. Each foreign establishment shall designate only one US agent and may designate the US agent to act as its official correspondent.

4) Upon request from FDA, the US agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the US, and assist FDA in

scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the US agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

5) The foreign establishment or the US agent shall report changes in the US's name, address, or phone number to FDA within 10-business days of the change.

6) No device may be imported or offered for import into the US unless it is the subject of a device listing and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment.

7) The device establishment registration and device listing information shall be in the English language.

8) For each individual or organization identified by the foreign establishment (YTY group) under paragraphs (1) and (2) of this section, YTY group shall submit to FDA electronically the current FDA premarket submission number and any other identifying information that is known to the establishment for each device being imported or offered for import by the named individuals or organizations.

B. Premarket notification procedure:

1) To register the establishment, owner or operator of YTY group shall submit a premarket notification submission (510K) to the FDA at least 90 days before the proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which:
   a) is being introduced into commercial distribution for first time;
   b) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. These significant changes or modifications that require a premarket notification includes:
      i. A change or modification in the device that could significantly affect the safety or effectiveness of the device.
      ii. A major change or modification in the intended use of the device.

2) If medical device was filed for premarket notification submission by another person, is exempted from new premarket notification.

Note: Refer to YGD 0303 for the 510K Procedure

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C. Establishment registration:
1) Owners or operators of places of business that are involved in the production and distribution of medical devices intended for use in the United State (U.S.) are required to register annually with the FDA. This process is known as establishment registration (Title 21 CFR Part 807).

2) If the device requires premarket notification clearance or approval, have to wait until the submission (510K, PMA, etc.) is cleared or approved before register the establishment and list the device. Then, proceed to do the following:
   - Enter premarket submission number
   - Enter proprietary name(s)
   - Identify the activities that perform on or to the device

3) All establishments required to register must first visit the Device Facility User Fee website (DFUF) to pay the user fee. Once payment have made and received confirmation number for the payment (PIN & PCN), then can proceed to the FURLS website to complete the registration and listing requirements as below:

   Go to FURLS website: Medical device registration and listing → Device registration and listing – FDA → access electronic registration → select "Create new account" to create FURLS account (http://www.access.fda.gov/oaa/) → select device registration & listing module (DRLM) → register a medical device facility

4) All owners can access FURLS at any time throughout the year to update changes to the registration and listing information as those changes occur.
   Examples of changes listing include:
   - Another device being introduced into commercial distribution
   - A change to a previously listed device, such as where it is being manufactured
   - A previously-listed device is removed from commercial distribution or commercial distribution is resumed

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6.2 REGISTRATION PROCEDURE IN CANADA:

A. YTY group's obligations:

1) YTY group shall comply with ISO 13485: 2016. This compliance will be audited by a registered accredited by Health Canada.

2) YTY group shall ensure medical device meets all applicable requirements, and shall keep the objective evidences indicating that medical device meets those requirements.

3) YTY group shall apply for Medical Device Establishment License (MDEL) (for Class I) or Medical Device License (MDL) (for Class II and above) in Health Canada.

4) If YTY group (as a producer of Class I) does not apply for MDEL, YTY shall appoint a qualified importer or distributor with MDEL, before the device is marketed in Canada.

5) License Application of a facility.

6) Registration of a label.

B. Safety requirements:

1) YTY group shall classify the risk inherent of the device.

2) During device's life, its performance and characteristics shall not be deteriorated, or shall not be adversely affected by transportation or condition of storage.

3) YTY group shall ensure material used in production of medical device shall be compatible with other material that poses no risk to user. Design and packaging shall minimize any risk to user.

C. **Labeling requirement:** refer to YGD 1505

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D. Application for medical device license:

1) Minister may direct the YTY group to stop the sale of Class I medical device if it does not comply with requirements. But upon providing of requirements or taking the corrective action by YTY group, minister may lift the direction to stop the sale.
2) An application for a medical device license shall be submitted to the Minister by the YTY group of the medical device in a format established by the Minister and shall contain the following:
   a) The name of the device;
   b) The class of the device;
   c) The identifier of the device, including the identifier of any medical device that is part of a system;
   d) The name and address of the establishment where the device is produced;

3) An application for a Class II medical device license shall contain, in addition to the information mentioned above, the following:
   a) A description of the medical conditions, purposes of the use;
   b) A list of the standards complied with in the YTY group;
   c) A copy of the device label;
   d) A copy of the quality management system (QMS) certificate certifying that the quality management system under which the device is manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485:2016;

4) YTY group shall ensure any "significant changes" in medical device license amendment application are submitted and audit shall verify that.

E. Quality Management System Certificate:

1) The Minister shall recognize a person as a registrar for the purpose of issuing or renewing QMS certificates if the person:

   a) Has sufficient training, experience and technical knowledge in the design and manufacturing of the medical devices and in the effective implementation of QMS to determine whether a QMS satisfies a standard.

   b) Conducts quality management system audits and issues, renews, suspends, and cancels quality management system certificates in accordance with the applicable guidelines and practices established by the ISO 13458:2016.

2) The minister may send the registrar a written notice that corrective action is required within a certain timeline.

3) If an application for medical device license is submitted by YTY group (a non-Canadian manufacturer) the minister may recognize a regulatory authority and conformity assessment body of a foreign country only if it has the ability to determine whether the device meets the applicable requirements. The minister (upon request) released the list of recognized regulatory authorities and conformity assessment bodies of foreign countries.

6.3 REGISTRATION PROCEDURE IN AUSTRALIA:

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A. Non-Australian manufacturer (YTY group) :

1) YTY group shall provide Conformity assessment from European notified body or from TGA.

   a) Conformity assessment (explained below; section D) is accepted if provided under:
      i. EU Notified Body, under "EU Medical Devices Directive "
      ii. Issued in Australia: TGA, EC MRA and EFTA MRA.

2) YTY group shall provide Declaration of Conformity (DoC) (explained below; section E).
3) YTY group shall classify the device based on Australian classification rules.
4) YTY group shall appoint an Australian sponsor.

B. Sponsor:

1) In Australia, sponsors take responsibility for the import, supply, or export of medical device. A sponsor shall be resident or carrying a business in Australia.
2) Both sponsor and YTY group shall be identified with the name and address on the packaging of the device or in document supplied with the device.
3) Sponsor shall request technical files from YTY group.
4) Sponsor shall confirm the Quality Management System documentation and records in relation to the device are retained by YTY group for at least 5 years.
5) Australian sponsor shall participate in MDSAP.
6) Australian sponsor is responsible for include (register) medical devices for YTY group in the Australian Register of Therapeutic Goods (ARTG). Sponsors are required to register YTY group that they represent and to obtain a Client ID for YTY from the TGA.

C. Australian Register of Therapeutic Goods (ARTG) and CE marking:

1) All medical devices including class I shall be included in the ARTG before supplying in Australian market. Inclusion in the ARTG is "Marketing authorization".

2) Marketing authorization (inclusion ARTG) is granted only to the Australian sponsor. Non-Australian manufacturers such as YTY group will need to assist the sponsor through the provision of information. A sponsor is not permitted to import a device until market authorization has been granted. YTY group procedures shall ensure that product is not released for export and supply to Australia unless the Australian sponsor has been issued with a "Certificate of Inclusion in the Australian Register of Therapeutic Goods" that identifies each kind of medical device that has been approved for supply to the Australian market. This can be found in the TGA website.

D. Conformity Assessment Procedures:

1) The Australian sponsor is responsible - to obtain information from the YTY group when requested from Therapeutic Goods Act (TGA).

2) The Australian sponsor shall ensure:

   a) They have available sufficient information to substantiate compliance with the regulatory requirements and ensure this information can be obtained from YTY group within 20 working days.
   b) An appropriate conformity assessment procedure has been applied to the medical device by the YTY group, and the conformity assessment remains valid until device is in the Australian market.
   c) Obtain a copy of conformity assessment from YTY group.
   d) Submitting the conformity assessment to TGA.
   e) Apply to include the medical device in the Australian Register of Therapeutic Goods (ARTG).
   f) Sponsor shall prepare for ongoing monitoring once device is included in ARTG and sponsor shall provide samples of the device to the TGA once it is requested.

E. Declaration of Conformity:

1) In Australia, the conformity assessment procedures require YTY group to make a Declaration of Conformity (DoC) in accordance with Australian legislative requirements.
2) The Australian DoC includes:

   a. YTY group verifies that the device name and type are in accordance with Australian conformity assessments procedure.
   b. The Global Medical Device Nomenclature System (GMDN) code (a 5-digit code) and classification of the device.
      i. GMDN is given by regulatory bodies as a nomenclature system to help identifying the medical device
      ii. YTY Industry provides GMDN before the medical device is approved.
      iii. TGA only liaise with the GMDN code to request information/amendments.
      iv. In Australia, GMDN codes are included on all:
         1) Entries in the ARTG.
         2) Australian Declarations of Conformity.

3) Australian sponsor are urged to seek the advice of YTY group and their DoC in order to verify the GMDN code before submitting an application to the TGA.

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F. Vigilance :

1) The vigilance responsibility is on the Australian sponsor.

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6.4 REGISTRATION PROCEDURE IN BRAZIL

A. Non-Brazilian manufacturer (YTY group):

1) YTY group shall obtain approval from The Brazilian Health Regulatory Agency (ANVISA) prior to selling their products in Brazil.

2) The regulatory requirements for obtaining approval are similar to those found in the European.

3) YTY group shall appoint a company that holds a Company Working Allowance permit from ANVISA as Brazil Registration Holder (BRH).

4) YTY group shall appoint a Brazilian importer/distributor (separate from BRH).

5) YTY group shall provide below documents to BRH for registration:

   a) Classify its medical device based on Annex II of Brazilian Resolution RDC 185/2001 published by ANVISA.
   b) Provide design and technical files.
   c) Provide Certificate of origin.
   d) Provide Letter of authorization.
   e) Provide a Declaration of Conformity (DoC).
   f) Propose labeling and IFU to BRH to keep on file in case of later ANVISA audit.

6) According to Brazilian Legislation, the Good Manufacturing Practice (BGMP) certification is a prerequisite for medical device registration that will be provided by YTY group to BRH.

B. Brazilian Registration Holder (BRH) :

7) BRH is regulatory representative of YTY group. Brazilian Regulation RDC 81/2008 allows registration holders to give authorization to YTY group to import products.

8) BRH acts as a liaison between YTY group and ANVISA.

9) BRH is responsible for registration of medical device in Brazil and is identified on the device registration.

10) BRH is responsible for controlling Brazilian Good Manufacturing Practice (BGMP).

11) It is recommended BRH and importer/distributor to be two separate identities. In case in future YTY group decides to change the importer/distributor, and BRH is recommended not to be involved with selling.

12) BRH shall apply for "Marketing Authorization" from ANVISA. For class I and II, "Notification" is required as a simplified market authorization. Notification has no expiry date. ANVISA reviews

registration application. If approved, ANVISA will publish registration number in the Diário Oficial da União (DOU).

13) BRH provides access to device documentations and submissions for ANVISA.

14) BRH requests for BGMP quality system inspections on YTY group behalf and shall submit self-inspection reports to ANVISA.

15) BRH coordinates with importer/distributor to produce "Import authorization letter". BRH shall send a notarized letter authorizing importer/distributor can begin importing the device into Brazil.

16) BRH shall submit the Letter of Authorization, registration application and technical files to ANVISA. YTY group will provide these documents for BRH.

17) BRH shall respond to health authorities, about any malfunctions, adverse events, situations presenting a serious threat to public health, alerts, field actions, and other events that represent a health risk and that are related to its products.

18) In case YTY group wants another BRH, Brazilian Resolution RDC 102/2016 allows the "registration transfer" to another BRH. However, transfer requires cooperation of previous BRH to sign the "transfer contract" and ask ANVISA to cancel the registration under their name. ANVISA will issue a new registration number once the transfer to another BRH is approved. But registration will carry the original validity date.

C. Importer/distributor :

19) Importer/ distributor 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.

6.5 REGISTRATION PROCEDURE IN JAPAN

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A. Non-Japanese manufacturer (YTY group):

1) YTY group shall ensure its QMS complies with MHLW Ordinance No. 169. Most class I devices do not require QMS conformity assessment. However some including Class I New devices require QMS conformity assessment.

2) YTY group shall appoint a Japanese representative: a licensed Marketing Authorization Holder/Designated Marketing Authorization Holder (MAH/ D-MAH) in this circumstances it is the customer who sells in Japan as YTY is OEM

3) YTY group shall register the "design and manufacturing facilities" besides other requirements to PMDA.

4) For all devices, a reimbursement application shall be filed with Economic Affairs Division of MHLW if applicable.

5) Specifications accepted in Japan: JIS, ISO and ASTM.

B. Foreign Manufacturer Registration (FMR) application:

1) Registration process is determined by medical device's classification and it is "Japan Medical Device Nomenclature (JMDN)".

2) For registration in PMDA following documents shall be submitted to receive FMR:

   a) For Class I devices, submit "Pre-Market Submission" to Pharmaceutical and Medical Devices Agency (PMDA). This is a "Notification" and no review/assessment by the PMDA will be conducted.
   b) For Class II (Specified Controlled) devices, submit "Pre-Market Certification" application to a Registered Certified Body (RCB) authorized to issue certifications. All documents must be in Japanese.
   c) Business number registration form to obtain a business number and its serial code.
   d) Self-Declaration of medical condition of the senior manager representing YTY group.
   e) Personal history of the responsible person in YTY group to be registered.
   f) Picture/drawing showing the building within the scope of registration.

3) Once YTY group recommends beginning of renewal process at least 5 months in advance of expiry of FMR certificate.

4) FMR can be submitted by YTY group or by MAH/D-MAH.

5) The PMDA often accepts the results of clinical trials conducted outside Japan if the investigation conforms to Japan's Good Clinical Practices.

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C. Japan Medical Device Nomenclature (JMDN codes) :

1) The MHLW maintains a database of generic medical device descriptions with associated Japan Medical Device Nomenclature (JMDN) codes. This system is similar to the US FDA system of product codes or Global Medical Device Nomenclature (GMDN) system.
2) Familiarity with the JMDN database and fluency in Japanese are essential to determine your device's code. If your device's code does not exist, products must go through a new device pathway, and classification is determined by risk according to the classification rules in Yakusyokuhatsu No. 0720022. However, final determination of your device classification would be made by the MHLW.

6.6 Notification to Regulatory Authorities on Changes

6.6.1 Japan

YTY shall communicate with the Marketing Authorization Holder about the change when the Registered Manufacturing Site plans such changes, so that the Marketing Authorization Holder could take any necessary regulatory actions mentioned in PMD Act 23-2-5.1, 23-2-5.11, 23-2-5.17, 23-2-23.1, 23-2-23.6, 23-2-23.7.

Examples of changes:

- Design;
- Composition;
- Raw material;

• Sterilization method;
• Manufacturing method;

- Manufacturing site;
- Patient or user safety features;
- Operating Parameters or conditions for use;
- Indication for use;
- Shelf life;
- Performance Specification;

Marketing Authorisation Holder (MAH) responsible to notify the Japan PMDA regulatory authority of the change.

6.6.2 Australia (TGA)

Australia sponsors responsible to register with Australia (TGA) for ARTG and report to ARTG if there is a change. He is required to notify their assessment body of:

A proposed substantial change to their QMS.

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6.6.3 Brazil (ANVISA):

YTY shall inform the Legal Manufacturer (customer) for any changes or modification in marketed device. Changes involving medical devices already approved by ANVISA, shall be submitted for a new approval [Brazilian Law nº 6360/76 - Art. 13] by the Legal Manufacturer. Changes/modifications that shall be submitted are those ones classified as significant change, which affects: a) features of safety and effectiveness, including measures to communicate information (ex. residual risk); b) identification of the device or its manufacturer or manufacturing site; c) indication for use, including its purpose, patient type (adult, pediatric, newborn) or environment to be used (domestic, hospital, ambulance, etc.); e) device classification; f) technical specification of the device, including composition and other operational/technical/physical features; g) manufacturing method.

- Sterilization method;
- Structural material / composition;
- New or additional manufacturer;
- Manufacturing method;
- Manufacturing site;
- Operating parameters or conditions for use;
- Patient or user safety features;
- Sterile barrier packaging material;
- Stability or expiration claims;
- Design;
- Labels and instructions of use (if modification is regarding information);
- Commercial name;
- Indication for use;
- New software version;
- Commercial presentation;
- Inclusion of a new device in a family of medical devices already approved;
- Inclusion of new accessories.

6.6.4 United States (FDA):

YTY is responsible for On Line FURLS updates for the 510K device listing, importer information and brand at the time the change occurs.

6.6.5 Canada

When there is a change YTY shall submit to the Minister, in a format established by the Minister, an application for a medical device license amendment including the information and documents set out in section 32 that are relevant to the change [CMDR 34].

YTY shall annually before November 1 and in a form authorized by the Minister, furnish the Minister with a statement signed by the manufacturer or by a person authorized to sign on the manufacturer's behalf describing any change to the information and documents supplied by the manufacturer with respect to the device, other than those to be submitted under section 34 or 43.1 [CMDR 43].

If YTY discontinues the sale of the medical device in Canada, the licensee shall inform the Minister within 30 days after the discontinuance, and the license shall be cancelled at the time that the Minister is informed [CMDR 43(3)].

Subject to section 34, if a new or modified quality management system certificate is issued in respect of a licensed medical device, YTY shall submit a copy of the certificate to the Minister within 30 days after it is issued [CMDR 43.1].

YTY to notify Health Canada on the changes/ renewed MDSAP Certificate. YTY to send Form 202 along with the revised MDSAP certificate to Health Canada.

Form 202 - https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/quality-systems-13485/form-f202-submission-new-modified-quality-management-system-certificate-medical-devices.html)

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6 RECORDS

7.1 Registration Flow Chart by Country	YGD 0405/01
7.2 Country Compliance Matrix	YGD 0405/02

Title: Registration Provision Procedure
Effective: 30/03/2023
Revised By: Shangari

Document No.: YGD 0405
Revision: 3
Approved By: Punitha

Reason For Change

Old Revision	*Current Revision*	*Effective Date*	*Page Affected*	*Revision Description*	*Provided By*	*Approved By*
Nil	0	16/11/2018	All	New Procedure	Mohadeseh	Punitha
0	1	17/08/2020	All	Add record	Pei Leng	Punitha
1	2	17/10/2020	10, 11	Adding Clause 6.6	Pei Leng	Punitha
2	3	30/03/2023	12	Adding new phrase in Clause 6.6.5	Shangari	Punitha

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