Botswana Medicines Regulatory Authority

Approved By: _____ _____

Mr. Bathusi Kgosietsile
Director - Product Evaluations and Registration

Date of approval (DD/MM/YY)

Revision status sheet

Page	Changes made	Issue No	Process owner	Reviewer's name	Date

Table of Contents

1. Purpose

The purpose of this guideline is to provide guidance to those submitting applications for registration of Medical Devices including In Vitro Diagnostic medical devices (IVDs) through the notification process.

2. Scope

i. The guidelines are applicable for class A medical devices including IVDs.

ii. The guidelines are applicable to all veterinary use only medical devices.

iii. The guidelines are applicable for general laboratory equipment and consumables.

Out of Scope

i. The guidelines exclude high risk (Class B, C and D) medical devices including IVD.

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

3.1.1 Accessory

An accessory is a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.

3.1.2 Act

Medicines and Related Substances Act. 2013

3.1.3 Applicant

The applicant shall be a legal manufacturer or registered company or entity in terms of Companies Act requesting for service and taking responsibility for ensuring the medical devices and IVDs' requirements are in compliance with the laws and regulation in force in Botswana. If the applicant is not a resident in Botswana, then he/she shall appoint a Local Technical Representative (LTR) also referred to as Authorized Representative who must be residing in Botswana or company incorporated in Botswana.

3.1.4 Authority

Means Botswana Medicines Regulatory Authority

3.1.7 Conformity Assessment

Means a systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

3.1.8 Distributor

Any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

3.1.9 Dossier

Means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrate quality, safety and performance of the finished medical device.

3.1.10 General Laboratory Equipment and Apparatus

Tools, devices, and instruments commonly used in a laboratory setting to conduct experiments, perform tests, or carry out various scientific procedures. These items are essential for measuring, mixing, heating, cooling, and analysing substances, as well as ensuring accurate and reliable results. They are typically not specialized for one specific type of analysis but are versatile and applicable across multiple disciplines, including chemistry, biology, physics, and medicine.

Examples of general laboratory equipment and apparatus include:

a) **Beakers**: Used for mixing, stirring, and heating liquids.

b) **Flasks**: Such as Erlenmeyer flasks, used for holding and mixing chemicals.

c) **Pipettes**: Instruments used to transport a measured volume of liquid.

d) **Balances**: Devices for measuring the mass of substances.

e) **Microscopes**: Instruments used to observe small objects or organisms.

f) **Centrifuges**: Machines that separate components of a mixture by spinning them at high speeds.

g) **Bunsen burners**: Used for heating substances.

h) **Test tubes**: Small cylindrical tubes used to hold, mix, or heat small quantities of substances.

i) **Autoclaves**: Used for sterilizing equipment and instruments.

j) **pH meters**: Devices used to measure the acidity or alkalinity of a solution.

3.1.11 Importer

Any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

3.1.12 Intended use/purpose

The objective intent of the manufacturer regarding the use of a device, process, or service as reflected in the specifications, instructions and information provided by the manufacturer of the medical device.

3.1.13 In Vitro Diagnostic

Means a medical device whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens delivered from the human body and animals principally to provide information for diagnostic, monitoring or compatibility purposes. They include reagents,

calibrator, control materials, specimen's receptacles, software, general laboratory equipment and related instruments or apparatus or other articles and are used for examples, for the following test purposes; diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological state.

3.1.14 Label

Means written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

3.1.15 Labelling/information supplied by the manufacturer

Means written, printed or graphic matter affixed to a medical device or any of its containers or wrappers or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

3.1.16 Local Technical Representative

A company incorporated in Botswana and authorized by BoMRA to operate in medical devices. The company should have received a written mandate from the manufacturer to act on his behalf for specified tasks regarding the latter's obligations under Botswana's legislation.

3.1.17 Manufacturer

A legal person or company that carries out at least one step of the manufacture of a medical device, which includes the responsible person and/or company that designs and/or manufactures a medical device with the intention of making the medical device available for use, under his/her/its name, whether or not such medical device is designed and/or manufactured by that person or on behalf of that person by another person(s).

3.1.18 Manufacture (manufacturing)

All operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, assembling, packaging, re-packaging and labelling of medical devices regulated under MRS Act.

3.1.19 Medical device

It means any instrument, apparatus, implement, machine, appliance, implant, in vitro

reagent or calibrator, software, material or other similar or related article -

a) intended by the manufacturer to be used, alone or in combination, for humans or animals for-
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
   iii. investigation, replacement, modification or support of the anatomy or of a physiological process;
   iv. supporting or sustaining life;
   v. control of conception;

vi. cleaning, disinfection or sterilization of medical devices; or

vii. providing information for medical or diagnostic purpose by means of in vitro examination of specimens derived from the human body; and

b) which do not achieve its primary intended action in or on human or animal body by pharmacological, immunological or metabolic means but which may be assisted in its intended function by such means.

3.1.20 National Standard

Means a standard as prescribed by the Botswana Bureau of Standards (BOBS) under the Standards Act.

3.1.21 Notified Product

Means medical devices, in-vitro diagnostic devices, veterinary use only medical devices and general laboratory equipment that has been granted market authorization through notification process.

3.1.22 Quality Management System

Means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

3.1.23 Recognized Standards

Means national or international standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

3.1.24 Reference Regulatory Authority

NRAs recognised by BoMRA as per Policy "Recognition and-or Reliance on Information on Medical Devices including IVDs from Regional and International Regulatory Agencies **BOMRA-ER-MED-Policy No.1** available on BoMRA website

3.1.25 Unique Device Identification System (UDI system)

A system that is intended to provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using AIDC and, if applicable, its HRI) based upon standard, with the UDI-DI of that unique identifier being also linked to a jurisdiction-specific public UDI database. For more information on the fundamental concepts of the unique device identification system, see IMDRF/WG UDI/N7Final:2013.

3.1.26 Unique Device Identifier (UDI):

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI (Device Identifier) and UDI-PI (Production Identifier).

Note: The word "Unique" does not imply serialization of individual production units.

3.2 ABBREVIATIONS

The following abbreviations shall apply:

3.2.1 **AIDC**: Automated Identification for Data Capture

3.2.2 **BoMRA: Botswana Medicines Regulatory Authority**

3.2.3 **BRIMS:** BoMRA Regulatory Information Management System

3.2.4 **BSE:** Bovine Spongiform Encephalopathy

3.25 **DoC:** Declaration of Conformity

3.2.6 **FDA:** Food and Drug Administration

3.2.7 **GMDN:** Global Medical Devices Nomenclature

3.2.8 **HRI:** Human Readable Information

3.2.9 **ISO:** International Organization for Standardization

3.2.10 **IVD:** In Vitro Diagnostic

3.2.11 **LTR:** Local Technical Representative

3.2.12 **MAH:** Market Authorization Holder

3.2.13 **MRSA:** Medicines and Related Substances Act

3.2.14 **NRA:** National Regulatory Authority

3.2.15 **QMS:** Quality Management System

3.2.16 **RRA:** Reference Regulatory Authority

3.2.17 **TSE:** Transmissible Spongiform Encephalopathy

3.2.18 **UDI:** Unique Device Identifier

4. GENERAL REQUIREMENT

This section describes application procedures and provides other useful information to applicants. Applicants are therefore advised to carefully read this section before compiling dossiers and assembling applications ready for submission to BoMRA. Therefore, the applicant shall take note of the following pointers when preparing a dossier for submission:

4.1 Data Presentation

All technical dossier submission for notification applications shall be submitted through BRIMS Self Service Portal at https://brims.bomra.co.bw/. The folders should be named as per the technical dossier requirements for medical device. The prepared dossier must contain all sections. Where

there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading.

The applicant should create all PDF files directly from source whenever feasible rather than creating them by scanning. PDF documents produced by scanning paper documents are far inferior to those produced directly from the source document, such as a Word document, and thus should be avoided if at all possible. File should not have any security setting, specifically:

i. File must not have password protection preventing the file from opening

ii. File should be set to allow printing, selecting text and graphics, and adding or changing notes and form fields

4.2 Language

All applications and supporting documents shall be in English. If any of the supporting documents is not in English, a verified translated document should be provided.

4.3 Responsibility of the applicant

The applicant as per the definition indicated on 3.1.3 shall be responsible for the product, information supplied in support of the application for registration, renewal and variations thereof. Whenever any serious safety concerns are noted, the applicant shall take appropriate actions including but not limited to informing the Authority, withdrawing registration, recalling the product from the market or revising labels by adding precautions or warnings.

4.4 Responsibility of Local Technical Representative (LTR)

The LTR as indicated in the definition section shall be responsible for:

4.4.1 Monitoring the device on the market and inform BoMRA immediately after the detection of any problem relating to a registered device such as serious manufacturing defects which may endanger public health.

4.4.2 Facilitating communication between the applicant and BoMRA on regulatory matters relating to the medical devices.

4.4.3 Handling device recalls.

4.4.4 Providing technical support and services to users of registered device (s), where applicable.

4.4.5 Any other responsibilities assigned by the manufacturer.

4.5 Applications

All applications for notification shall be made online through BRIMS Self-Service Portal at https://brims.bomra.co.bw .

4.6 Acceptable Products for Notification

The following products are applicable for notification registration pathway: -

a) Medical devices and IVDs in class A as per the rules of classifications covered in section 4.5.2 of these guidelines.

b) Veterinary use only medical devices covered in this guideline.

c) General laboratory equipment and apparatus

4.7 Classification system for General Medical Devices

4.7.1 Medical devices, including in vitro diagnostics (IVDs), are categorized into four risk classes (A, B, C, D). If a device falls under multiple classification rules, the rule that results in the highest risk classification will apply. However, the Authority retains the discretion to determine the device's classification

4.7.2 For detailed information on the risk classification rules for general medical devices, please refer to the "**Guideline for Medical Device Classification**" (**BOMRA/ER/MED/P04/G05**).

4.7.3 For specifics regarding the risk classification of IVDs, consult the "**Guideline for In Vitro Diagnostic Medical Devices Classification**" (**BOMRA/ER/MED/P04/G06**).

4.8 Medical Devices Grouping Requirements for Product Registration

Each product registration application shall contain **only one group** of medical devices as prescribed in the **Guideline for Grouping of Medical Devices including IVDs BOMRA/ER/MED/P04/G07.**

Each submitted application shall contain only one of the following groupings of medical devices:

i. A single medical device

ii. one medical device family

iii. one medical device system

iv. one medical device group

v. IVD Test Kit

vi. IVD Cluster

4.9 Product Dossier

A separate and complete product dossier in an electronic format is required for each application or as per the grouping category indicated above 4.6 section. Applicants are required to arrange the application dossier as per section 5 of this guideline. Failure to

arrange the application dossier accordingly might lead to rejection of the application at the time of submission.

4.10 Processing of applications

4.10.1 Once an application has been accepted and screening fees paid the processing of application will take 3 months.

4.10.2 Incomplete applications will be queried for additional data and returned back to the applicant for rectifications. There shall be a maximum of 3 query cycles.

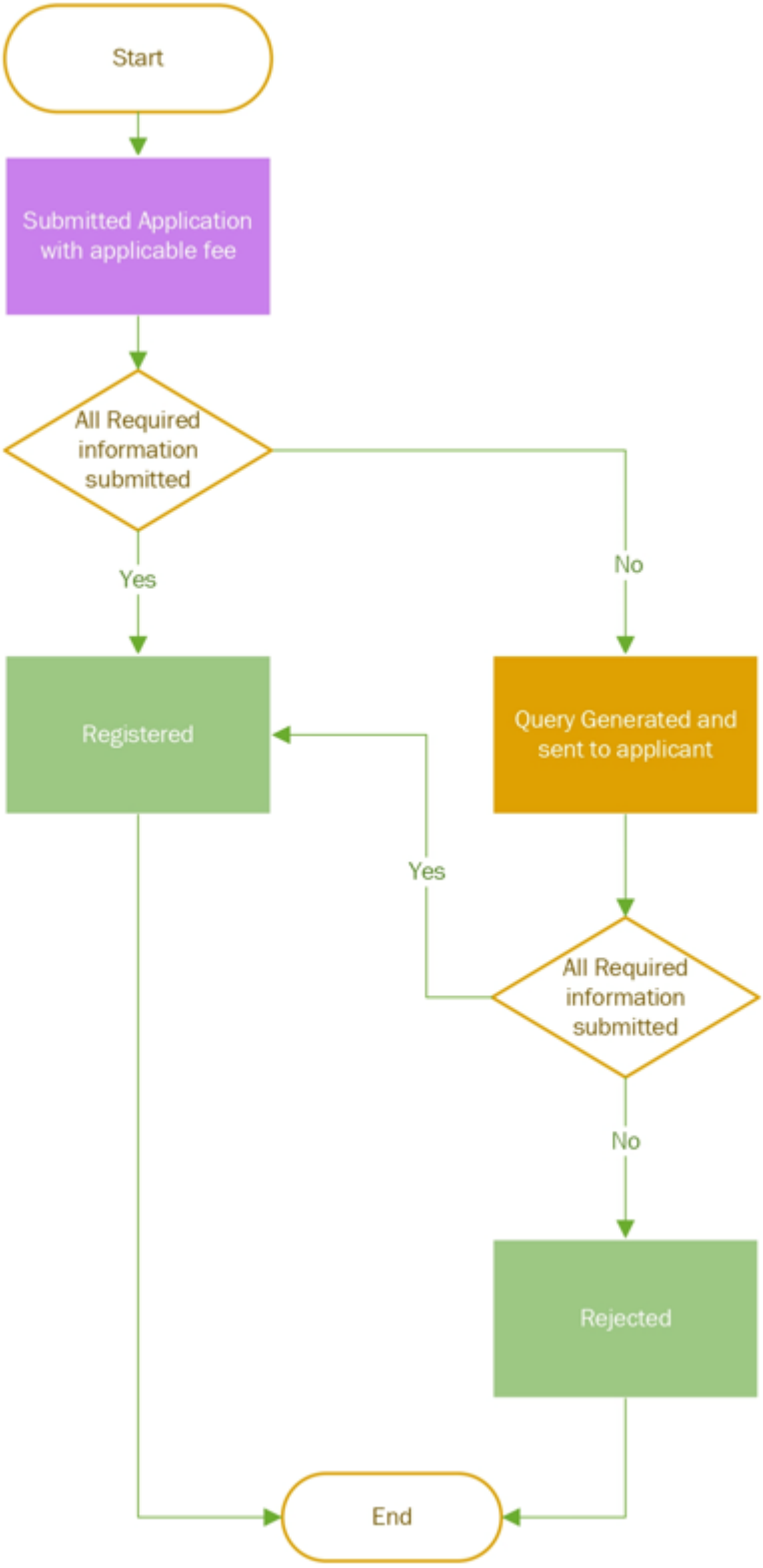
4.10.3 Once a query or a request has been raised, the processing time shall halt until after the response to the query has been received. Applicants will be required to respond to the queries response within 30 days, failing which the application will be rejected.

4.10.4 Once the query has been resolved and a product is found to comply with all prescribed requirements for safety, quality and performance, it will be notified and an approval letter/registration certificate will be issued through the online platform.

4.10.5 If the applicant experiences difficulty in responding in full or within the specified timeframe, they should contact the Authority to discuss the queries as soon as possible after receipt of the input request for information/clarification.

4.10.6 If the applicant wishes to resubmit the application in future, it will be processed as a new application.

4.10.7 A summary of processing registration notification applications is shown in the diagram below.



4.11 Registration of the device

When a device is found to have complied with all the prescribed notification registration requirements, the applicant will be informed of that effect. A certificate of registration together with such conditions as BoMRA may determine shall be issued.

4.12 Validity of registration

The registration of a medical device shall be valid for five (5) years unless suspended or revoked by BoMRA or terminated by the registrant. The validity of notification shall be subject to: -

a) Payment of annual retention fees as prescribed in the current MRSA Regulation, 2019, Schedule 5

b) Submission of post-marketing surveillance reports.

c) Submission of adverse event reports associated with the use of devices.

4.13 Termination of Notification

BoMRA may give reasons in writing to suspend or revoke the notification of a device or amend the conditions of its notification. The applicant may issue BoMRA a written notice and reasons to terminate registration of a device as per the Withdrawal of Marketing Authorization and/or registered/listed medical devices including IVDs guideline (BOMRA/ER/MED/P08/G01).

4.14 Appeals

Any person aggrieved by a decision of the Authority in relation to any application for notification may make representations in writing to BoMRA.

4.15 Changes to a notified product

a) The Authority should be informed of any significant change(s) that could reasonably be expected to affect the safety or effectiveness of a medical device including In vitro Diagnostics.

b) MAHs are required to submit a "Variation" application. Please refer to **Medical Devices Variation Guidelines-** BOMRA/ER/MED/P09/G01 for the types of changes and required documents to be provided for submission.

c) Certain changes are so fundamental that they alter the terms of the registered medical device and consequently cannot be considered as a change. For these cases a new dossier must be submitted. Any other change(s) should be notified immediately to the Authority.

4.16 Renewals

Applications for renewal of notification shall be made before the expiry of existing registration by submitting all the applicable requirements indicated in the renewal guidelines.

4.17 Payment of fees

a) Every application shall be accompanied by appropriate fees as specified in Medicines and Related Substances Regulations of 2019, Schedule 5, currently in force at the time of application.

b) Notification fee (Screening fee) shall be paid at the time of lodging an application for notification.

c) Any application that will not be accompanied by appropriate fees will not be accepted.

d) All fees are non-refundable once paid to the Authority

5. Documentation Requirements

Documentation requirements apply to all acceptable products for notification mentioned above in section 4.5.1.

5.1 Application form

The application form for notification shall be completed online through BoMRA Customer Self-Service Portal at https://brims.bomra.co.bw.

5.2 Authorization Letter for Local Technical Representative (LTR)

In cases where the manufacturer is not based in Botswana, a letter of authorization as per **template 1** should be made by the manufacturer of the medical device for registration indicating the agent (LTR) responsible for the import, distribution, sale and post registration activity of the product in Botswana.

5.3 Product Details

a) Description of the product including features, accessories, intended uses and users. The description should state;

i. State the generic name, brand name of the device.

ii. The intended uses of the product (i.e. conditions that require its usage)

iii. The intended users (i.e. professional or general users)

iv. The targeted population (Children, Adults, Elderly, any Gender criteria)

v. Any associated products that work together with the product (examples; reagents, controls, accessories etc)

vi. The number of unit products in a commercial pack

vii. Storage conditions for the device. This should be based on results of stability studies conducted (where applicable).

viii. Recommended shelf-life or service life of the device supported with stability studies.

ix. UDI number of device (if applicable)

x. Reagents associated with the device (IVDs)

xi. Specimen type to be used with the device (IVDs).

b) 3D-Pictures of the device in the commercial pack whereas, all sides of the devices are clearly visible.

5.4 Manufacturer Information

5.4.1 Provide valid certificate of compliance to ISO 13485 standards or its equivalent or manufacturing license from the manufacturer(s) of the devices.

5.4.2 Local manufacturers (based in Botswana) have to be licensed with BoMRA prior to notification of their products. This also applies to the manufacturers involved in the final manufacturing process like assembly, resizing, cutting or packaging.

5.4.3 Used products which have been refurbished by a third party who is not the original manufacturer of the devices, then, that third party shall bear the responsibility of the manufacturer described in this guideline.

5.4.4 Manufacturing process flow chart.

5.5 Declaration of Conformity

The manufacturer should attest that its medical device complies fully with all applicable Essential Principles for Safety and Performance as documented in a written DOC as per **template II**.

5.6 Certificate of Compliance with Recognized Standards

The applicant should submit the applicable certificate of ISO 13485 or equivalent, product certificate, TSE/BSE risk free attestation letter, standards for sterilization (such as ISO 11135, ISO 11137, ISO 17665 etc.) with information on sterilization method (s) and certificate of conformity in line with the DoC declared.

For Active medical devices

- Evidence of certification to electrical safety standards e.g. IEC 60601

For Sterile medical devices

- Sterility validation report which indicates the mode used for sterilization e.g. Ethylene Oxide, Gamma ray, Steam.

For medical devices with a measuring function

- Evidence of certification or medical device metrology or equivalent.

5.7 Product Samples

Two (2) product samples in their commercial presentation as and when requested.

5.8 User Manual or Instructions for use

Give a concise summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed.

5.9 Risk Management Report

A summary of a risk management report or evidence that risk analysis is part of the manufacturer's risk management plan. Applicable for active, sterile and devices with a measuring function.

5.10 Post-Marketing Surveillance Plan

Prior to and after placing the product on the market, the manufacturer should put a process in place, as part of its quality management system, to assess the continued conformity of the device's safety and performance through the post-marketing phase. This process will include complaint handling, post-market vigilance reporting, and corrective and preventive actions. Applicant needs to provide a Post-Marketing Surveillance Plan addressing to Botswana market.

6.0 Labelling Requirement

Medical devices offered or imported for sale or use in Botswana must meet the labelling requirements as per the labelling guideline (**BOMRA/ER/MED/P04/G03**) This guidance is to be used in the preparation of labelling material for regulated products in all risk classifications. Furthermore, symbols to be included in the medical devices label shall meet the minimum requirements stated in the ISO standards for labelling requirement.

Template 1
Letter of Authorisation Template

[To be printed on Company Letterhead of Product Owner]
Medical Devices Unit
Department of Products Evaluation and Registration
The Botswana Medicines Regulatory Authority

[Date]

Dear Sir/Madam,

Subject: Letter of Authorization for [LTR (Company Name)]

We, [name of Product Owner (Company Name)], as the Product Owner, hereby authorize (Company Name), as the LTR to deal with all matters for the regulation of medical devices to the Botswana Medicines Regulatory Authority (BoMRA)on our behalf.

This authorization shall apply to the following medical devices:
[List containing product names of medical devices]

We also authorize [(Company Name)] to make declarations and to submit documents on our behalf, regarding the above medical devices. These declarations and submissions are made pursuant to the requirements of the MRSA Act & Regulations and any other applicable laws that may also be in force.

This authorization shall remain in effect until our notification to the Botswana Medicines Regulatory Authority in writing (either by postal mail or facsimile transmission) that the authorization is revoked.

We undertake to provide post-market support and assistance to the applicant as may be required in relation to any matter involving the above medical devices.

We acknowledge that any non-compliance with any registration condition issued by the Botswana Medicines Regulatory Authority in relation to medical devices registered on the Botswana Medical Device Register may result in the suspension or cancellation of the medical device registration.
We agree to assist the Botswana Medicines Regulatory Authority with any request for information on the above medical devices.

Yours Sincerely,

[Signature]
[Full Name and Title of Company Official]
[Name and address of company

Template II
Declaration of Conformity

[To be printed on Company Letterhead of Product Owner]

Name and Address of Product Owner:

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance.

Manufacturing Site:
(Physical manufacturing site(s) including sterilization site(s))

Medical Device(s):
(e.g., product name and model number)

Global Medical Device code and term for the device(s).
(Generic names used to identify all medical device products)

Risk Classification: e.g., Class B, rule
(Risk Classification of medical device(s) according to the classification rule, and the rule(s) used to determine the classification)

Quality Management System Certificate:
(Certification Body and Certificate Number, issue date, expiry date)

For Class B, Class C and Class D medical devices, declaration of conformity to either of the following QMS standards is mandatory:

☐ ISO 13485/ Quality Audit

☐ US FDA Quality System Regulations

☐ Japan MHLW Ordinance 169

Standards Applied:
(International standards; OR Regional Standard)

This declaration of conformity is valid from (Day Month Year)
Authorised Signatory:

_____ _____

Name, Position Date