Guidance for determining medical device application type

Health Canada Santé Canada

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Foreword

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, effectiveness or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of the regulations and other applicable guidance documents.

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Overview

Purpose

This document provides guidance to manufacturers on the different application types listed in the Medical Devices Regulations (regulations):

- medical device family
- medical device group
- medical device group family
- system
- test kit

Throughout this document, "application type" includes licence application types under Part 1 of the regulations and authorization application types under Part 1.1 of the regulations.

This document also provides guidance to manufacturers on how to determine whether certain medical devices, including components and parts, can be combined and submitted as 1 device licence or authorization application. This is set out in:

- sections 28 to 31 under Part 1 of the regulations and
- sections 68.05 to 68.09 under Part 1.1 of the regulations

Medical devices, including components and parts, that cannot be combined into any of these 5 combinations must be licensed under Part 1 or authorized under Part 1.1 individually. In this document, these devices are referred to as a "single medical device".

Note: For the purposes of this document, the term "parts" does not refer to "service parts", which are understood to be those used during the servicing or repair of a medical device.

Scope and application

This document applies only to medical devices that are subject to both the Food and Drugs Act (act) and the regulations. Some devices, such as veterinary medical devices, are subject only to the provisions of the act.

Medical devices authorized for use or sale under Part 2 (custom-made devices and medical devices to be imported or sold for special access) or Part 3 (medical devices for investigational testing involving human subjects) of the regulations do not require a medical device licence under Part 1 or an authorization under Part 1.1 of the regulations.

Throughout this document, any reference to an authorization refers to an authorization under Part 1.1 of the regulations (for medical devices for an urgent public health need).

Under Part 1 of the regulations, Class I medical devices are not subject to the device licence requirements of section 26. However, under Part 1.1 of the regulations, the manufacturer of a Class I medical device can hold an authorization or an amended

authorization to import or sell an authorized medical device, if they don't already hold an MDEL.

Before a Class II, III or IV medical device can be imported or sold in Canada, the manufacturer of the device must hold either:

- a licence or an amended licence, as per section 26 of the regulations or
- an authorization or an amended authorization under sections 68.12 and 68.13 of the regulations

This document is organized by application types that apply to manufacturers of non-in vitro diagnostic devices (non-IVDDs) and in vitro diagnostic devices (IVDDs).

Manufacturers must develop application submission strategies that comply with the regulations. Health Canada encourages manufacturers to document their structure rationale in the cover letter of their medical device licence or authorization application. A complete rationale should reference the relevant sections of the Regulations and available guidance. The rationale should also clearly explain how the proposed structure meets the regulatory requirements.

This document does not describe the requirements of a device licence or authorization application. For further information, refer to the following guidance documents:

- Guidance documents for medical devices
    - Draft IMDRF table of contents for medical device applications
    - Guidance on how to complete the application for a new medical device licence
    - Guidance on medical devices for an urgent public health need

Policy objectives

Health Canada wants to ensure that manufacturers have the necessary guidance to determine:

- if their medical devices, including components and parts, can be combined together and submitted as 1 device application
- the application type as a medical device family, medical device group, medical device group family, system, test kit or single medical device

This will help manufacturers submit the information that is specified in section 32 of the regulations or, if applicable, section 68.11 of the regulations. This allows Health Canada to assess the safety, quality and effectiveness of a medical device.

Background

Sections 28 to 31 of the regulations describe 5 situations when a medical device, including component or parts, is deemed **licensed** following a single successful application under Part 1.

Similarly, sections 68.05 to 68.09 of the regulations describe the same 5 situations when a medical device, including components or parts, is deemed **authorized** following a single successful application under Part 1.1.

Definitions

Most of the definitions in this guidance document are taken from the Medical Devices Regulations (regulations). To align with international standards, this guidance document also adopts many terms defined in the Principles of Labelling for Medical Devices and IVD Medical Devices (International Medical Devices Regulators Forum).

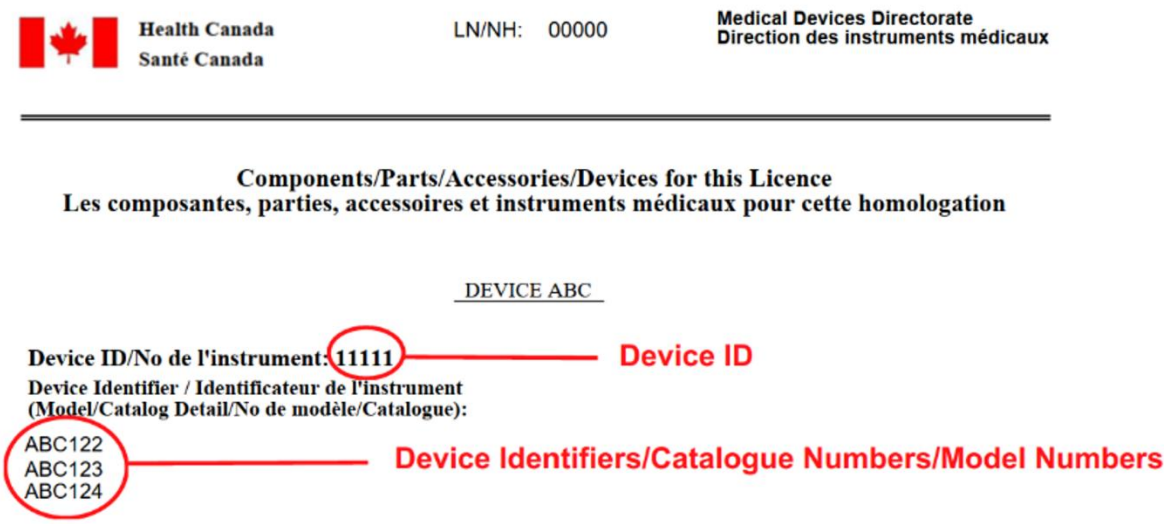
Authorization: An authorization that is issued under section 68.12.

Device ID: The device identification number assigned by Health Canada. This identification number appears on the issued licence or authorization.

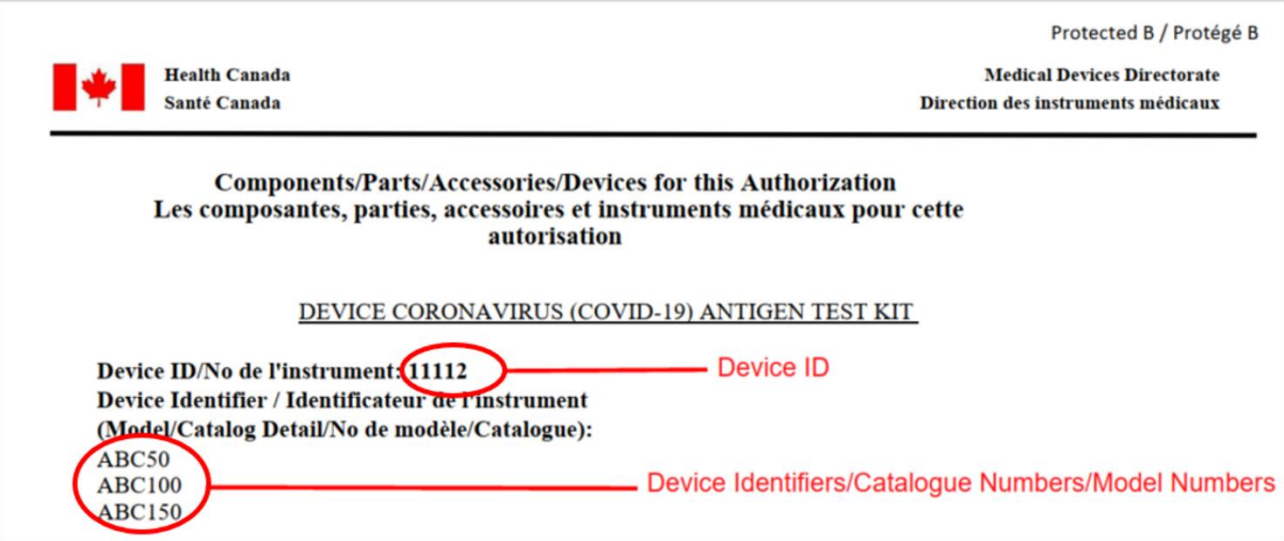
Note: A single device ID may encompass several device identifiers.

Identifier: A unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices.

Note: Examples of an identifier for a device are a catalogue, model, part number or software version.



This figure shows where the device ID and the device identifiers, catalogue numbers or model numbers are located on an issued medical device licence.



This figure shows where the device ID and the device identifiers, catalogue numbers or model numbers are located on an issued medical device authorization.

Indications for use: A general description of the disease or condition the medical device or IVD medical device will diagnose, treat, prevent, cure or mitigate. Includes a description of the patient population for which the medical device or IVD medical device is intended. (IMDRF GRRP WG/N52 FINAL:2019)

Note: The indications for use are generally labelled as such. They may also be inferred from other parts of the labelling, including the directions for use, precautions, warnings and bibliography sections.

Intended use/intended purpose: The objective intent regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. (IMDRF GRRP WG/N52 FINAL:2019)

Note: The intended use and intended purpose are also part of promotional or sales materials or statements, although these materials lie outside the scope of this document. The intended use can include the indications for use.

Manufacturer: *A* person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Medical device family: A group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use.

Medical device group: A medical device comprising a collection of medical devices, such as a procedure pack or tray that is sold under a single name.

Medical device group family: A collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group.

Off-the-shelf component or accessory: A product that is not specifically manufactured and/or designed to suit a particular medical device.

Note: Examples include commercial batteries and generic power cables.

Procedure kit (for instance, procedure pack, surgical tray): A collection of medical devices, that may or may not be made by the same manufacturer, such as surgical instruments, dressings or materials, that are packaged together for use in a range of surgical procedures in a particular clinical specialty.

Significant change: a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following:

a) the manufacturing process, facility or equipment;
b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;
c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and
d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry date.

Single medical device: A single device that is identified with a unique name by its manufacturer

System: A medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name.

Test kit: An in vitro diagnostic device that consists of reagents or articles, or any combination of these, and is intended to be used to conduct a specific test.

Application type for non-IVDDs

Single medical device criteria

A single medical device application type should only ever contain 1 device.

The medical device licence or authorization will only include **1 device ID** and **1 device identifier**. However, medical devices that vary in package sizes can be included on a single medical device licence or authorization. In cases where there is one medical device with multiple packaging sizes, there would be 1 device ID and multiple device identifiers on the same licence or authorization.

Example:

- Condoms sold in packages of 8, 12 and 20, as long as the individual pouch labelling satisfies the labelling requirements for products sold to the general public

A single medical device licence or authorization can include a medical device that is sold with accessories, as long as they do not qualify as medical devices in their own right.

Example:

- A Hearing aid sold with generic, off-the-shelf batteries (for example, size 312 batteries)

Note: If the component/accessory is a medical device in its own right and is manufactured, designed or labelled for use with a specific device, then the device and its components/accessories are not considered a single medical device. Refer to the definition for medical device system.

A single medical device licence or authorization can include multiple components or accessories if all the parts are sold within one package and are represented by a single device identifier, and are **physically connected at the time of sale**

Example:

- A guidewire and catheter that are pre-loaded and packaged together are considered a single medical device. However, a guidewire and a catheter that are packaged separately are considered a medical device system, as the guidewire and catheter qualify as 2 separate medical devices.

Additional information

Medical devices, parts or components that cannot be assigned to a system, medical device family, medical device group or medical device group family must each be licensed or authorized as a single medical device. This includes components or parts that are not

sold under the manufacturer's name or are not sold with the systems with which they can be connected.

Medical device family criteria

Medical device family members:

- are made by the same manufacturer
- have the same design and manufacturing process
- have the same intended use
- differ in shape, colour, flavour or size
- may have different brand names

Certain family members may serve as representative devices against which all key testing can be completed to support claims for all other devices in the family. Typically, these representative devices encompass the full range of possible specifications across the family. As such, the safety and effectiveness of the representative devices completely support all safety and effectiveness claims of all other devices in the family.

Example:

- For a family of stents, representative devices may include models with the smallest length and diameter and the model with the largest length and diameter (for instance, shortest thinnest, shortest thickest, longest thinnest, longest thickest – commonly known as four corner testing). Other dimensions, materials, intended use and manufacturing processes are identical.

Note: In general, all family members should qualify under the same Global Medical Device Nomenclature (GMDN) code. For more information on GMDN, consult the following document:

- Notice: Improving access to medical devices information

Design

The design philosophy of family devices should be supported by key testing of the representative devices that supports all other devices in the family.

Device family members

Examples:

- Cardiac resynchronization therapy devices that differ from each other only in minor software features (for example, increased number of programmable A/V pacing delays), where at least one model includes all of the available features
- Heart valves with sizes different from those already authorized on the same medical device licence or authorization (even though the introduction of these would be deemed a significant change and require a review of clinical evidence)

- Patient monitors that differ in combinations of optional input sockets (for example, support for connection to third party modules such as ECG, SpO2, CO2) or, for a given input, differ in vendor support (for example, ABC SpO2 input vs. XYZ SpO2 input)
- Patient monitors that differ only in feature sets enabled by software, where at least one model includes the full set of available features
- Bare esophageal stents made of the same material and that only differ in length or diameter of the stents and for which all stents are indicated for narrowing due to benign tumor

Not device family members

Examples:

- Any combination of Toric, monofocal, bifocal, extended depth, or trifocal intraocular lenses, as they have different optical designs and/or indications for use
- Infusion pumps with different pumping control mechanisms (for instance, syringe-based pump versus a peristaltic pump), as they do not share the same control mechanism
- Therapeutic ultrasound systems that rely on different operating principles, such as through thermal damage versus cavitation, to achieve their therapeutic effect
- Different left atrial appendage devices with design differences in structure (for example, fine mesh design versus fabric covered solid construction)
- Different models of endoprosthesis that use an alternate expansion mechanism (for example, nitinol self-expansion vs. balloon expansion)
- Cardiac resynchronization therapy devices from different generations of models with physical design differences or different software features that are not common across the different generations of models.

Materials

Key testing of the representative devices should support all devices in the family.

Device family members

Examples:

- Dental materials that only differ in colour
- A difference in the material of an external, non-patient contacting accessory (for example, the operator handle on a non-invasive ultrasound transducer)

Not device family members

Example:

- Esophageal stents of varying length and diameter, where some are bare and others are covered or partially covered, as the covering introduces a different key material

Intended use

The medical device family may have only 1 overall intended use. While individual family members may have more precise indications for use, in general they should be clinically equivalent.

Note: If the intended use statement is very broad or non-specific, the indications for use may be used to determine if the devices can be on the same family licence.

The intended use is determined from the medical device labelling and may also be inferred from the promotional material for that medical device. For information on labelling medical devices and defining intended use/indication for use, consult the following guidance documents:

- Labelling of medical devices, not including IVDDs
- Labelling of in vitro diagnostic devices

Device family members

Examples:

- Hearing aids that are intended to amplify sound and transmit sound to the ear for adults at different amplitudes for different frequencies to enhance hearing, and only differ in colour
- Bone plates that have the same intended use and indications for use, but vary in shape and size
- A single model of intra ocular lenses (IOLs) that have the same optical design, intended use and indications for use, and only differ in diopter
- Dual-chamber implantable cardioverter defibrillators and single-chamber implantable cardioverter defibrillators that have the same intended use and the same base software. In such cases, the dual-chamber device includes all functionality available in the single-chamber device and differs only in the number of cardiac leads. In this case, the specific indication for use for the single-chamber and dual-chamber devices may be different.

Not device family members

Examples:

- Wire guide A intended for use in the delivery of percutaneous catheters into the peripheral vasculature and wire guide B intended for use in the delivery of percutaneous catheters into the gastrointestinal tract and urinary tract
- Medical devices which have the same design, manufacturing process and materials, but do not have a clinically equivalent intended use.
- Dermal fillers that are sold under the same broad general intended use, for example, intended for injection into the dermis or subcutaneous tissue to temporarily restore facial volume, but where model alpha is indicated for correcting

deep nasolabial folds, and model beta is indicated for nasolabial folds and augment lips, cheeks, and chin.
- Drug-coated balloons/stents indicated for different anatomical targets (for example, below the knee vs. coronary) where safety and effectiveness are based on different clinical study data.
- Implantable cardioverter defibrillators and cardiac resynchronization therapy devices have different intended uses (for instance, different patient populations)

Manufacturing process

In general, family devices must have the same manufacturing process. This involves being supported by the same manufacturing process validation requirements.

Device family members

Examples (where all other medical device family criteria are met):

- Devices released from the sterilization process by either biological indicators or parametric release
- Devices that are sterilized using the same type of sterilization process (for example, ethylene oxide) but are subject to different manufacturing specifications (for example, cycles optimizations)

Not device family members

Examples:

- Devices sterilized using different sterilization methods (for example, ethylene oxide vs. steam)
- Sterile and non-sterile devices
- Devices where some are laser-cut from a solid Nitinol tube, and some are cast in a mold of the same geometry.
- Dermal fillers with different levels of cross-linking

Additional information

Under Section 30 of the Medical Devices Regulations (regulations), it is Health Canada's interpretation that each medical device must have its respective device identifier appear on the final licence or authorization in order to be licensed or authorized. However, only evidence concerning representative members of the medical device family may be needed during the application review process.

If a device, or subset of devices, listed on a family licence undergo a significant change and those same changes are not applied to the other devices on that licence, this may impact the eligibility of the changed device(s) on the family licence and may require a separate licence.

Medical device group criteria

A medical device group may only be labelled with a single device identifier that represents a collection of devices. Examples of medical device groups may include procedure kits and first aid kits. The Global Medical Device Nomenclature (GMDN) Agency has a complete definition of these terms.

Example:

- One cardiovascular procedure kit

Note: If there are other variations of the same kit (for example, different length catheters, different quantity of catheters), these variations would each be represented by a different device identifier. They would instead belong on a medical device group family licence or authorization.

Components of a medical device group **do not** have to be fabricated by the same entity. However, the person who meets the definition of manufacturer as set out in section 1 of the regulations must hold the medical device licence or authorization.

The devices within the medical device group may be labelled individually or provided in bulk form. However, the entire medical device group must be labelled and sold under a single name.

Example:

- An Acme Suture Tray, manufactured by Medical Devices Ltd., is a medical device group
    - This group contains a number of devices packaged together (for example, needles, suture thread, drapes, swabs, needle holder and other single-use disposable devices) for convenience to meet a specific purpose (for instance, wound closure).
    - Medical Devices Ltd., as the manufacturer of the group holds the licence, even when the group contains devices fabricated by others.

Devices licensed or authorized in a medical device group cannot be sold nor distributed outside the context of the group without a single or family medical device licence or authorization.

Example:

- An orthopedic implant instrumentation set contains disposable reamers, tibial spacers, screwdriver, drill guide and driver. If the manufacturer wishes to sell the disposable reamers separately, then the component must have its own single or family medical device licence.

Additional information

Under Section 31(1) of the regulations, a medical device group is deemed licensed if all the devices that constitute the group are individually licensed. Similarly, under section 68.09(1), a medical device group is deemed authorized if all the devices that constitute the group are individually authorized.

This allows a manufacturer to bundle some of their products, normally offered for sale individually, into promotional packages without needing additional licences or authorizations. Under these conditions, the individual medical devices must maintain the labelling and integral packaging (for instance, sterility) detailed in their licences or authorizations.

Medical device group family criteria

A medical device group family is composed of a collection of medical device groups that must:

- be made by the same manufacturer
- have the same generic name specifying their intended use, including the same intended use
- differ only in the number and combination of products that comprise each group

Examples of a medical device group family can include procedure kits and first aid kits. The GMDN Agency has a complete definition of these terms.

Examples:

- A medical device group family licence of Polyglycolic Acid Suture packs consisting of the suture, needle, scalpel, scissors and gauze are indicated for general soft tissue approximation and/or ligation. A similar pack with the same combination of medical devices that include a suture is indicated for superficial soft tissue approximation of the skin and mucosa only (not general). This pack cannot be included on the medical device group family licence as the 2 sutures do not have the same indications for use.
- Pro-Pack Surgical Kits are manufactured by ABC Surgical Supply Company. The kits are medical device groups containing a number of medical devices and other items (which are not medical devices) within them such as swabs, gauze, sutures and needles, of varying size and shapes. Although these components are individually packaged and labelled, most of these items are bought in bulk from their manufacturers to be sold only as part of the kits. ABC Surgical Supply Company may submit 1 licence application for the Pro-Pack Surgical Kits as a medical device group family. The kits are customized for various hospitals and different surgical procedures, but the inner components (medical devices included within the kits) are selected from a list of medical devices submitted with the group family licence application. This list is typically included in the cover letter or device description document.

Generic packs/trays sold without a defined intended use that are grouped for an indication (for example, obstetrics, cardiovascular) can be included under 1 medical device group family licence or authorization. The various medical device group family members may exist under a general overarching indication(for example, medical specialty), presuming that the generic packs/trays are otherwise the same.

Example:

- Procedure packs all indicated for use in cardiovascular procedures (for example, intended for use in major vascular procedures such as abdominal aortic aneurysms, femoral angiography), would be considered medical device group family members, presuming the pack design, indication for use (i.e., medical specialty), materials and manufacturing process are the same and supported by the same body of evidence.
- A medical device group family can include a variety of devices with different sizes, such as peripheral stents. Each packaged device can be considered a group, as it includes accessories with a main balloon catheter and implantable stent. The different packs come with different peripheral stents that vary in diameter and length. Although the names of the devices may be different, they should share a similar family name (for example, ACME 99 stiff and ACME 99 flex). Minor design differences may include catheters that differ in dimensions to accommodate different guidewires (0.014" and 0.035") and implantable stents that come in an array of different diameters and lengths

Additional information

The medical device name indicated for the medical device group family must appear, at least in part, on the label of each group. This can be a brand name or a generic name. Individual medical device names may contain additional descriptive phrases.

Under Section 30 of the regulations, it is Health Canada's interpretation that each medical device must have its respective device identifier appear on the final licence in order to be licensed. Similarly, under section 68.08, it is Health Canada's interpretation that each medical device must have its respective device identifier appear on the final authorization in order to be authorized.

However, only information concerning representative members of the medical device group family may be needed during the application review process.

Note: Under these conditions, the individual devices must maintain the labelling and integral packaging (for instance, sterility) detailed in their licences or authorizations.

Medical device system criteria

A medical device system is a medical device that includes a number of components or parts intended to be used together, but not necessarily all at the same time, to fulfil some or all of the medical device's intended functions.

A medical device system should be represented and sold under a common "system" name. This could be a generic system name (such as gynecological ultrasound system) or a trademarked/brand name (such as ABC Ultrasound System 1). It is recommended that the system name appear on the medical device labelling.

Note: Where components of a system have different names but must be solely used together under a specific system, these components must be included on the same system licence or authorization if any of the labelling explicitly states the specific system components are to be used together.

Example:

- ABC Implants manufactures the XYZ Implant as well as the AA delivery system. This delivery system must be used to deliver the XYZ implant. The instructions for use, provided with the XYZ implant, describe how to deliver the implant using the AA delivery system. The medical devices have different names, but because they constitute a dedicated system, they must reside on the same system licence.

A medical device system has a single overarching intended use statement.

Medical device system

Example:

- A radiofrequency (RF) ablation system consisting of a radio frequency (RF) generator, 2 RF electrodes and a power cart. The system's intended use is to cut and coagulate tissue. However, the RF generator also has an intended use of "for generation of RF on ABC system"; the RF electrodes state they are "intended for soft tissue and bone"; and the power cart is intended "to provide battery back to the ABC system."

Not a medical device system

Example:

- The ABC shoulder system includes humeral stems, humeral heads, screws and glenoids for anatomic shoulder replacement, as well as humeral cups, humeral liners and glenospheres for reverse shoulder replacement. These should not be on the same system licence. The reverse shoulder components are not expected to be used together with the anatomic components and have unique indications (they are indicated for use only when the rotator cuff is non-repairable).

There can only be 1 manufacturer for all system components. Components or parts of a medical device system that are labelled under a different manufacturer's name must be licensed or authorized separately.

Example:

- A breathing circuit device and tubing with the legal manufacturer, ABC Company, is compatible with ventilator systems from several different legal manufacturers, ABC Company and XYZ Company. Since the breathing circuit is compatible with ventilator systems from multiple legal manufacturers, it would be licensed separately. It would still be considered a compatible device and should be listed as such on the application form along with the related licence number.

Systems manufactured by the same manufacturer may include components that are also compatible with other systems made by that same manufacturer. The components need to appear on each system licence.

Examples:

- A foot-switch by manufacturer ABC may be compatible with multiple x-ray systems by manufacturer ABC. In these instances, the foot-switch should be listed on all system licences for which it is designed and labelled for use.
- Abutments by manufacturer XYZ may be compatible with multiple dental implant systems. The abutments should be listed on all dental implant system licences for which they are designed and labelled for use.

Additional information

All Class II, III and/or IV system components that are medical devices in their own right and are to be imported and/or sold in Canada are to be included on the licence or authorization. This includes replacement and spare device components, as well as consumables that may be available to the customer or end user.

In general, multiple devices sold as systems need to be licensed or authorized separately. In limited cases, complex groupings of devices sold as systems may reside on a family licence or family authorization. In these cases, the manufacturer is responsible for documenting clearly how they qualify for this option based on the family licence or authorization criteria.

Examples where a family licence or authorization is needed:

- Full featured Device A with features X, Y, Z, Device B with features X, Y and Device C with only feature X would be allowed on the same licence, provided the scientific evidence for Device A also covers Device B and C. There is 1 identifier for Device A, 1 for Device B and 1 for Device C. Any accessories are sold and always packaged together under the identifier for A, B or C only.
- Identical medical devices that differ only by software feature availability, as long as the differences in features do not confer any difference in intended use, associated risks or the risk mitigations applied.

Examples where separate system licence or authorization is needed:

- Full featured System A with features X, Y, Z, System B with features X, Y and System C with only feature X would be allowed on the same licence, provided that A, B and C have equivalent safety and effectiveness evidence. There is 1 identifier for System A, 1 for System B and 1 for System C, and any components, parts, or accessories that qualify as devices in their own right are sold and packaged under their own identifiers.
- A CT scanner system is designed such that different models are marketed with access to a different subset of the identical features as controlled solely by software configuration (controlled by the manufacturer). All other aspects are identical, including intended use. Compatible accessories can be sold separately with their own identifiers.

Application type for IVDDs

Single medical device criteria

A single medical device licence or authorization type should only ever contain 1 device.

Examples are:

- generic, open architecture, standalone analyzer
- single FISH Probe

The final medical device licence or authorization should only include **1 device ID** and **1 device identifier**. However, devices that vary in package sizes can be included under 1 application for a single medical device licence or authorization. In cases where there is one device with multiple packaging sizes , there would be 1 device ID and multiple device identifiers on the same licence or authorization.

Example:

- Glucose test strips that are sold in packages of 10, 50 and 100

Additional information

Medical devices, parts or components that cannot be assigned to a system, test kit, and a medical device family must be licensed or authorized individually. This includes components or parts that are not made by the manufacturer of the devices or systems with which they are connected.

Test kit criteria

In vitro diagnostic test kits can reside on the same test kit licence or authorization if they meet **all** of the following criteria:

- same intended use
- same test design
- same reagent formulation
    - differ only in size configuration or
    - only have minor differences in instrument-specific characteristics not likely to impact the performance of the test (for example, reagent volumes, number of tests, on-board stability of the reagent cartridge, cartridge design)
        - applies to test kits that only differ in the instrument platform they run on

Note: A device ID will be created for each test kit and its dedicated platform.

As a general rule, a significant change to 1 test kit on a test kit licence or authorization with more than 1 test kit will impact all the test kits on that licence or authorization.

Examples:

- A rapid HIV test kit that comes in different size configurations (for example, a box of 25, 50 or 100 individual pouches, or just individual pouches).
- A manufacturer introduces the next generation of analyzer for use with their test kits. The only change to the test kits is the configuration of the assay cartridge. The test kit with the new configuration may be added to the existing test kit licence.
- Various formats (for example, midstream, test strip, cassette) of at-home pregnancy tests cannot reside on the same licence. Although all formats are indicated to determine human chorionic gonadotropin (hCG) levels in urine specimens, they do not all use the same test design.
- Three individual test kits that detect either IgA, IgG or IgM antibodies to the same virus cannot reside on the same test kit licence. Although they are associated with the same virus, each assay detects a different analyte (for instance, IgA, IgG or IgM). Safety and effectiveness of each assay are supported by different studies since they are not clinically equivalent. Therefore, each assay will require its own test kit licence.

All the reagents or articles of the test kit are sold under a single manufacturer's name.

The reagents or articles need not be sold as a complete package. Some reagents or articles may be sold separately due to a requirement for different shipping temperatures. Individual reagents can also be sold separately as replacement items for the kit. Each medical device that can be sold as a replacement item must have a unique device identifier and will be listed separately on the issued licence or authorization.

Test kits manufactured by the same manufacturer may include reagents that are compatible with other test kits.

Example:

- The ABC Diagnostic company manufactures a multi-analyte quality control that can be used with the ABC Diagnostic's test kit A and test kit B. The multi-analyte quality control can be listed on all test kit licences for which it is designed and labelled for use. This control will have a consistent device ID across all licences.

A test kit licence does not include any instrumentation needed to perform the test (for example, analyzers).

Additional information

If reagents or articles of the test kit (for example, controls, buffers) are available to the end user separately, their name and device identifier must be included on the licence or authorization application form. The test kit licence or authorization will include all the device identifiers.

Medical device family criteria

Medical device family members:

- are made by the same manufacturer
- may differ in size and/or concentration
    - for example, level 1, 2, 3 controls for Troponin are intended to be used with multiple Troponin assays from different manufacturers
- may have different brand names

Manufacturing processes, design and intended use must be the same between members of the family and supported by the same body of evidence.

Device family members

Examples:

- Blood glucose meters that share the same design and intended use but have different brand names.
- Blood glucose meters that share the same design and intended use but differ in features that do not affect the device's performance, such as wireless connectivity or data storage capacity.

Not device family members

Examples:

- Controls that have the same intended use but are composed of different analytes.
- A multiplex assay detecting Treponema pallidum (TP) and human immunodeficiency virus (HIV) and the corresponding single analyte tests (TP only and HIV only) cannot be considered family members.

For more information, consult:

- medical device family criteria for non-IVDDs
- Guidance for the interpretation of significant change for a medical device

Analyzers may be listed on the same family application if they have the same design. They may differ in throughput, software, sample volume or performance characteristics (for example, sensitivity) for the compatible reagents.

Example:

- The Space EXL 200 analyzer is a modified version of the SPACE EXL analyzer. It is functionally identical to the SPACE EXL, except it does not have a Reagent Management System, which results in reduced on-board sample storage capacity. Both analyzers can be included on the same licence application type as a family.

Additional information

Under Section 30 of the Medical Devices Regulations (regulations), it is Health Canada's interpretation that each medical device must have its respective device identifier appear on the final licence in order to be licensed. Similarly, under section 68.08, it is Health Canada's interpretation that each medical device must have its respective device identifier appear on the final authorization in order to be authorized.

However, evidence of compliance to the regulations by only representative members of the medical device family is needed during the application review process.

Medical device system for IVDDs criteria

A medical device system includes a number of components or parts intended to be used together to fulfil the device's overall intended functions.

A medical device system should be represented and sold under a common "system" name. This could be a generic system name (for example, immunoassay system) or a trademarked/brand name (for example, ABC Immunoassay System). Health Canada strongly recommends that the system name appear on the medical device labelling.

The labelling should demonstrate how each component for the system is needed to fulfil the device's overall function. For example, an analyzer/meter and its corresponding test kit/panel/test strip that are dedicated exclusively to each other can be considered a system.

If an analyzer/meter is designed to support multiple different assays/panels/test strips provided by the same manufacturer, with the same brand name but with different intended uses, the assays/panels/test strips and the analyzer/meter should be licensed or authorized as test kits or single medical devices. The analyzer/meter should not be on a system licence or authorization with multiple assays/panels/test strips unless the intended use of the system is overarching and the results from the different assays/panels/test strips are used together to support the intended use.

Examples:

- TRUE GLUTM Blood Glucose Monitoring System comprising TRUE GLUTM test strips, TRUE GLUTM controls and TRUE GLUTM meter. All components are needed to work together to obtain a glucose reading. All components are all identified with the same brand name.
- The ABC analyzer is designed to be used with the ABC HCV assay. The analyzer and the assay work together to provide an HCV result. If the analyzer were designed so new and different assays could be added to the analyzer menu in the future, it would need to be licensed under a single device licence and the assays as separate test kit licences.
- A meter with 3 different test strips each measuring different analytes (for example, glucose, follicle stimulating hormone and vitamin B12) that do not need each other

to fulfil each other's function. These cannot be considered a system even if they have the same brand name.

- A blood glucose monitoring system includes both glucose and ketone strips. The intended use for the monitor might be "an aid to monitor the effectiveness of diabetes control." The glucose and ketone strips may be licensed with the meter as a medical device system since they support the overarching intended use of the system.

There can only be 1 manufacturer for all system components. Components/parts of a medical device system that are labelled under a different manufacturer's name must be licensed or authorized separately.

An open architecture-type analyzer (an instrument that is manufactured with general-purpose features and is not intended for use with a specific test) is not considered a system component.

Systems manufactured by the same manufacturer may include components that are compatible with other systems.

Example:

- A wash buffer may be compatible with multiple different platforms/analyzers. In these instances, the cross-compatible system component should be listed on all system licences for which they are designed and labelled for use.

Additional information

As stated in Section 28 of the regulations, all the components of the system that are produced by the system manufacturer are deemed licensed when the system is licensed. Similarly, as stated in section 68.06, all the components of the system that are produced by the system manufacturer are deemed authorized when the system is authorized. For example, on-board reagents licensed as part of a system are deemed to have been licensed and can be sold with the system.

However, if the on-board reagents are meant to be sold separately as replacement reagents for the same system, then the medical device name and identifier must be included on the licence or authorization application form. The licence or authorization will include all the device identifiers.

Additional examples

Manufacturers may combine different IVD devices as listed in the following cases.

Blood grouping reagents, tissue typing/HLA typing reagents

Blood grouping reagents can be grouped under a family application by phenotype/group antigen, as long as they are the same type of reagent (for example, all monoclonal antibodies (human)).

Example:

- Reagents for ABO determination (A1, A2, B, O, A1B and A2B phenotypes) may be bundled under 1 licence application, and Kell phenotype reagents would be under a different application (K-k+, K+k-, K+k+, Kp (a+b-), Kp (a-b+) and Kp (a+b+) phenotypes).

The same approach may be applied to tissue typing/HLA typing reagents, which can be grouped by class specificities.

Example:

- Reagents used for Class I typing will require a family licence application while Class II reagents will require a separate family licence application.

Drugs of abuse panel tests

"Drugs of abuse" tests are used to obtain a drugs of abuse profile of the test sample based on the detection of a single drug or multiple drugs and metabolites in human urine. The configuration between these medical devices can vary in the number of drugs included and the format presentation (for example, cassettes vs. cups vs. strips).

These medical devices can be combined under one device licence or authorization application by format (for instance, an application for cups, an application for cassettes, an application for strips).

The device identifiers associated with a drugs of abuse test should include the product codes for the various drugs, rather than a device identifier specifying the number of drugs tests contained within a device. For example, device identifiers "AMP", "FEN" and "OXY" would represent amphetamine, fentanyl and oxycodone.

The final licence or authorization should include each drug's specific device identifier and the final product labelling would list all device identifiers (for instance, AMP FEN OXY) included in the respective medical device. The labelling for the test would still need to meet the requirements outlined in section 21(1) of the regulations.

Disinfectants as medical devices

Since March 16, 2018, Health Canada has classified high-level disinfectant and sterilant solutions (including contact lens disinfectants) intended for use on medical devices as medical devices.

For more information, consult the following guidance document:

- Safety and effectiveness requirements for high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices

Health Canada recommends that high-level disinfectant and sterilant solutions for general use be licensed or authorized as single medical devices on their own medical device licence or authorization. This is the most appropriate regulatory pathway for these types of disinfectant/sterilant solutions that are typically:

- not manufactured for a specific medical device system
- compatible for use with multiple medical devices

However, a high-level disinfectant or sterilant cartridge that is specific to only 1 medical device system should be added to the system licence or authorization through an amendment application if it is from the same manufacturer.

References

Health Canada guidance documents

- Labelling of in vitro diagnostic devices
- Guidance for the labelling of medical devices, not including in vitro diagnostic devices - Appendices for the labelling of soft contact lenses, decorative contact lenses and menstrual tampons

International documents

- Principles of labelling for medical devices and IVD medical devices
    - (International Medical Device Regulators Forum)