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January 12, 1999

To: Medical Devices Stakeholders

Subject: Guidance For the Interpretation of Sections 28 to 31: Licence Application Type

The *Medical Devices Regulations* set out the requirements governing the sale, importation and advertisement of medical devices. The goal of the Regulations is to ensure that medical devices distributed in Canada are safe and effective and meet quality standards. These Regulations were published in *Canada Gazette II* on May 27, 1998, and implementation began on July 1, 1998.

This document, entitled, *Guidance For the Interpretation of Sections 28 to 31: Licence Application Type* sets out the Programme's guidance for Industry on how to combine devices for licensing. It is intended to replace the draft guidance document "Guidance On How to Determine The Device Licence Type" published on February 13, 1998.

This new guidance document provides guidance to manufacturers in determining whether certain medical devices including components and parts can be combined together and submitted as one device licence application as set out in sections 28 to 31 of the Regulations. It expands on the definitions in the Medical Devices Regulations and provides examples of acceptable device combinations which could be submitted as one device licence application such as a system, test kit, medical device group, medical device family, or medical device group family.

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For more information on the interpretation of sections 28 to 31 of the *Medical Devices Regulations* please contact:

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Attachments

Health Canada Santé Canada

PROGRAMME DES PRODUITS THÉRAPEUTIQUES THERAPEUTIC PRODUCTS PROGRAMME

Therapeutic Products Programme

OUR MISSION: To ensure that the drugs, medical devices, and other therapeutic products available in Canada are safe, effective and of high quality.

Programme des produits thérapeutiques

NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

Therapeutic Products Programme
GUIDANCE DOCUMENT

Guidance For the Interpretation of Sections 28 to 31: Licence Application Type

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Table of Contents

1 Introduction

1.1 Purpose

This guidance document is intended to provide guidance to MANUFACTURERS in determining whether certain MEDICAL DEVICES including components and parts can be combined together and submitted as one device licence application as set out in sections 28 to 31 of the Regulations. This document will expand on the definitions in the *Medical Devices Regulations* and provide examples of acceptable combinations which could be submitted as one device licence application such as a SYSTEM, TEST KIT, MEDICAL DEVICE FAMILY, MEDICAL DEVICE GROUP or MEDICAL DEVICE GROUP FAMILY.

MEDICAL DEVICES including components and parts that cannot be combined into one of the above combinations must be licensed individually. For the purpose of this document these devices are referred to as a single medical device.

1.2 Background

Under section 26 of the *Medical Devices Regulations,* the MANUFACTURER of a Class II, III or IV MEDICAL DEVICE must hold a licence or an amended licence for a device before it can be sold in Canada.

Sections 28 to 31 of the *Medical Devices Regulations* describe six situations when a MEDICAL DEVICE, including component or parts, is deemed licenced following a single successful application.

A device licence application submitted as a SYSTEM, TEST KIT, MEDICAL DEVICE FAMILY, MEDICAL DEVICE GROUP or MEDICAL DEVICE GROUP FAMILY assumes the highest classification. As a result the required information for that device class, as detailed in section 32 of the *Medical Devices Regulations,* must be provided for all constituents to support the licence or amended licence application. The appropriate quality system requirements for devices grouped under one application must be met by all the constituent devices.

1.3 Scope

An exact discussion of all types of devices is not possible within the scope of this document. If additional questions or concerns remain about a particular device licence type, the MANUFACTURER is urged to contact the Manager, Licensing Services Division, Medical Devices Bureau at (613) 957- 7285.

This document will not describe the content of a device licence application. For further information refer to the guidance documents "Guidance on How to Complete the Application for a New Device Licence, GD013, " "Guidance on How to Complete the Application for an Amended Device Licence, GD015," and "Preparation of a Premarket Review Document for Class III and IV Device Licence Applications, GD008."

1.4 Definitions

COMPONENT - One of several possibly unequal subdivisions into which something is or is regarded as divided and which together constitute the whole. A component may also be referred to as a part or an accessory.

AUTOMATED ANALYZER - For the purpose of this document they are defined as devices which produce an analytical result from an applied sample by performing functions beyond the mere analytical reading of a generated signal, such as performed by a simple spectrophotometer, gamma counter, luminometer, fluorometer, etc. Automated analyzers can be further divided into the following three types:

(1) CLOSED-SYSTEM ANALYZER - An analyzer that is intended by its manufacturer to be used only in combination with the reagents that it also provides. These reagents are often referred to as Original Equipment Manufacturer (OEM) supplied or recommended reagents. Closed-system analyzers may be batch analyzers, random-access analyzers or the newer multichannel batch analyzers. In many cases, closed-system analyzers give the user no programming capabilities other than data management and no access to the assay protocol(s). Assay menu expansion capability often exists on these systems, that is, additional assay protocols can be installed on the instrument as they are developed. In this document, these called referred to as "expandable closed- system analyzers." Instruments that are designed with a set number of measurable parameters and do not have the capability to be modified during their lifetime are referred to in this document as "non-expandable closed-system analyzers."

(2) OPEN-SYSTEM ANALYZER - An analyzer that is manufactured with general purpose features for use only with secondary reagents. Secondary reagents are reagents produced for use with specific analyzers by suppliers other than an OEM supplier. Secondary reagents may be marketed and labelled for one specific analyzer or may claim multiple analyzers. Most open-system analyzers give the user programming capabilities for inputting preferred assay protocols. An example would be an automated microplate analyzer that can be adapted by the user to commercially available microplate test kits.

(3) PARTIALLY-CLOSED-SYSTEM ANALYZER - An analyzer that is intended by its manufacturer to be used both in combination with the reagents that it provides (OEM reagents), or with secondary reagents for the analysis of analytes for which the manufacturer does or does not provide reagents. In the latter case, the analyzer serves as a general purpose analyzer in an open system.

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 distinguishing it from similar devices.

INDICATIONS FOR USE - A general description of the disease(s) or condition(s) that the device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the device is intended. The indications include all the labelled uses of the device, for example the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, the part of the body or type of tissue applied to or interacted with, frequency of use, physiological purpose and patient population. The indications for use are generally labelled as such, but may also be inferred from other parts of the labelling, including the directions for use, precautions, warnings and bibliography sections.

INTENDED USE - The intent of the manufacturer as expressed in the labelling of devices under their control. Intent is also expressed by both the promotion and the circumstances surrounding the distribution of the device.

IN VITRO DIAGNOSTIC DEVICE (IVDD) - A medical device or a product subject to section 3.1* of the *Medical Devices Regulations*, that is to be used *in vitro* for the examination of specimens derived from the human body.

> ** Section 3(1): These Regulations apply to an in vitro diagnostic product that is a drug or that contains a drug as if the product were a medical device.*

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

MEDICAL DEVICE - An article, instrument apparatus or contrivance, including an accessory, part or component of one, that is manufactured, sold or represented for use in:

> a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in a human being;
> b) the restoration, correction or modification of a body function or the body structure of a human being;
> c) the diagnosis of pregnancy in a human being; or
> d) the care of a human being during pregnancy and at and after the birth of a child, including the care of the child.

It includes a contraceptive device but does not include a drug.

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 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.

MEDICAL DEVICE NAME - Any information necessary for the user to identify the device and to distinguish it from similar devices.

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 specification 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.

SOFTWARE - The set of instructions used to control the actions or output of a medical device, to provide input to or output from a medical device, or to provide the actions of a medical device. This definition includes software that is imbedded or permanently a part of a medical device, software that is an accessory to a medical device, or software that is itself a medical device. This does not include software used only for data management.

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. This includes an IVDD system, but does not include processing devices that support numerous different assays and may be designated by manufacturers as systems.

TEST KIT - An *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.

2 Interpretation of Sections 28 to 31: Licence Application Type

There are six situations when medical devices could be combined under one licence application. These situations are discussed below.

2.1 A System

A SYSTEM refers to a MEDICAL DEVICE, including an *in vitro* diagnostic device, that is sold under a single name and contains a number of COMPONENTS intended to be used together to fulfil some or all of the device's intended functions. COMPONENTS not sold under the SYSTEM name cannot

be licensed with the SYSTEM, even when they are intended to be used together.

All the components of the SYSTEM that are produced by the MANUFACTURER of the SYSTEM are deemed licensed when the SYSTEM is licensed. COMPONENTS of the SYSTEM that are made by another MANUFACTURER must be licensed separately. All the COMPONENTS of a SYSTEM must be listed on the licence application by MEDICAL DEVICE NAME and IDENTIFIERS. The application must provide documentation and information on all COMPONENTS of a SYSTEM.

For example, the ABC Hip Replacement System can be submitted as one licence application as a SYSTEM because all the COMPONENTS are made by the same MANUFACTURER, ACME Medical Inc., and are sold under the SYSTEM name. All components must be identified on the licence application.

Similarly, the Urine HIV System, an *in vitro* diagnostic device SYSTEM, contains a specimen collection container (with preservative), a first-line enzyme immunoassay (EIA) and a confirmatory Western Blot assay. One licence application for the SYSTEM can be submitted because all the COMPONENTS are made by the same MANUFACTURER and are sold under the SYSTEM name. All components must be identified on the licence application.

In the IVDD industry, the reference to system often designates automated ANALYZERS and their respective reagents or TEST KITS. A licence application can be submitted for a SYSTEM that encompasses the ANALYZER and all TEST KITS and reagents provided all TEST KITS and/or reagents and the ANALYZER are made by the same MANUFACTURER and are sold under a single name. Any TEST KIT or reagents not sold under the system name must be licensed individually.

For automated analyzers and their associated reagents or TEST KITS, one or more applications may be submitted based on the risk class of the different assays. For example, an application as a system may contain the ABC HIV-1/-2 EIA, the ABC anti-HCV, the ABC PSA EIA, the ABC CA125 EIA, and the ABC CK-MB with the ABC ANALYZER. In this case, the requirements for Class IV IVDDs would apply to all constituents. Alternatively, two applications could be submitted. One class IV application for the ABC HIV-1/-2 EIA and the ABC anti-HCV with the ABC ANALYZER and one Class III application for the ABC PSA EIA, the ABC CA125 EIA, and the ABC CK-MB with the ABC analyzer.

On-board reagents licensed as part of a SYSTEM are deemed to have been licensed and can be sold separately as replacement reagents for the same system.

2.2 Test Kits

A TEST KIT only applies to *in vitro* diagnostic devices. It can consist of reagents or articles, or any combination of these, that are used together to conduct a specific test. The kit does not include the instrumentation needed to perform the test, such as an ANALYZER.

All the reagents or articles of the TEST KIT that are produced by the same MANUFACTURER are deemed to be licensed when the kit is licensed. These reagents or articles need not be sold as a complete package; they may be sold separately as replacement items for the kit. However, the device names and IDENTIFIERS of all the constituents of the TEST KIT must be listed on the device application form, in order to be licensed with the kit.

For example, controls and dilution and washing buffers specifically required to perform the Free PSA EIA are licensed with the TEST KIT, provided the MANUFACTURER'S name is on the label of the individual items. These items may be offered for sale separately as replacement items for the kit.

2.3 A Medical Device Family

A MEDICAL DEVICE FAMILY is a group of medical devices that are made by the same manufacturer, that differ in only shape, colour, flavour or size, that have the same design and manufacturing process and that have the same INTENDED USE.

As a principle, materials, labelling , manufacturing processes, design and performance specifications cannot be significantly different between the members of the family. Please refer to "Guidance for the Interpretation of Significant Change, GD001."

The INTENDED USE of a device is determined from the INDICATIONS FOR USE included on the device labelling. It can also be inferred from both the promotion and the circumstances surrounding the distribution of the device.

Section 30 states that when one member of a MEDICAL DEVICE FAMILY is licensed, all other devices identified on the licence application are deemed licensed. For Class III or IV devices, documentation and information need only be provided for a representative member of the family.

Unless a significant change is made to all devices, any device within the family, that is significantly changed, can no longer be included on the family licence as part of that family and therefore requires its own licence.

For example, an application for a MEDICAL DEVICE FAMILY could be issued a licence for the Gastrostomy Catheters manufactured by MD Canada Inc. because these catheters share a common method of production and common INDICATIONS FOR USE, are fabricated from the same materials and are listed on the licence application.
The device name indicated for the MEDICAL DEVICE FAMILY must appear, at least in part, on the label of each of the member devices. Individual device names may contain additional descriptive phrases.

2.4 Medical Device Group

A MEDICAL DEVICE GROUP refers to a MEDICAL DEVICE that is composed of a collection of MEDICAL DEVICES, such as a procedure pack or tray, that is labelled and sold under a single name.

The devices in a MEDICAL DEVICE GROUP are not required to have the same MANUFACTURER or to be labelled with the name of the group. Devices deemed to be licensed in a MEDICAL DEVICE GROUP cannot be sold outside the group without a SINGLE MEDICAL DEVICE licence.

The constituent devices in the MEDICAL DEVICE GROUP must be listed by device name and IDENTIFIER on the licence application form. Bulk items may be repackaged without labelling for inclusion in the group. The application must provide documentation and information on all constituent devices of a GROUP.

For example, the Acme Suture Tray, manufactured by Medical Devices Ltd., is a MEDICAL DEVICE GROUP that can be submitted as one application. This group contains a number of devices packaged together for convenience to meet a specific purpose (e.g. wound closure). Some of the devices in the group are packaged and labelled, while others are in bulk form. All of the devices identified and listed on the licence application for the MEDICAL DEVICE GROUP will be deemed licensed with the group. The licence is held by the MANUFACTURER of the group, even when the group contains devices manufactured by others.

Subsection 31(1) states that a MEDICAL DEVICE GROUP is deemed licensed if all the devices that constitute the group are made by a single MANUFACTURER and are individually licensed. This allows a MANUFACTURER to bundle some of their products, normally offered for sale individually, into promotional packages without the need for additional licences. Under these conditions, the individual devices must maintain their labelling as detailed in their individual device licences.

Subsection 31(2) states that all the devices that constitute a licensed MEDICAL DEVICE GROUP are deemed licensed when sold with the group. A device licensed as part of a MEDICAL DEVICE GROUP requires an additional SINGLE MEDICAL DEVICE licence if offered for sale individually.

2.5 Medical Device Group Family

A MEDICAL DEVICE GROUP FAMILY refers to a collection of MEDICAL DEVICE GROUPS that are made by the same MANUFACTURER, have the same generic name specifying their INTENDED USE, and differ only in the number and combination of products that comprise each group.

Licensing the groups as a family allows the MANUFACTURER to customize MEDICAL DEVICE GROUPS for particular hospitals or physicians, while maintaining the same generic name and INTENDED USE. When one member of a MEDICAL DEVICE GROUP FAMILY is licensed, all other MEDICAL DEVICE GROUPS in the family are deemed licensed.

The MEDICAL DEVICE GROUPS in a MEDICAL DEVICE GROUP FAMILY do not have to be listed by name in the licence application. However, the application must identify all possible constituent MEDICAL DEVICES and their IDENTIFIERS.

The device name indicated for the MEDICAL DEVICE GROUP FAMILY must appear, at least in part, on the label of each of the member devices. Individual device names may contain additional descriptive phrases.

2.6 Single Medical Device

A SINGLE MEDICAL DEVICE is identified with a unique name by its MANUFACTURER and is sold as a distinct packaged entity.

MEDICAL DEVICES, parts or COMPONENTS that cannot be assigned to a SYSTEM, a TEST KIT, a MEDICAL DEVICE FAMILY, a MEDICAL DEVICE GROUP, a MEDICAL DEVICE GROUP FAMILY must be licensed individually. This includes COMPONENTS or parts that are not made by the MANUFACTURER of the devices or SYSTEMS with which they are connected.

Medical devices that are licensed for sale as part of a SYSTEM MEDICAL DEVICE GROUP or MEDICAL DEVICE GROUP FAMILY must have a SINGLE MEDICAL DEVICE licence if they are sold outside the system, group or group family.

Devices that vary in size or package sizes are not considered to fall within the MEDICAL DEVICE FAMILY, and one licence application for a SINGLE MEDICAL DEVICE should be filed for the various size or package sizes. For example, condoms which are sold in packages of 8, 12 and 20.

3 Additional Examples of Licence Application Types

Appendix 1 presents a series of questions and answers to assist MANUFACTURERS in understanding and applying the regulations discussed in this guidance document. This question-and-answer series shows the decision-making process required to determine when devices can be combined under one licence application and when individual licence applications are required. There are three flowcharts presented in Appendices 2 to 4 to illustrate this process.

Appendix 1 - Questions and Answers on Licence Application Types

The instructions in this document apply only to MEDICAL DEVICES that are subject to both the *Food and Drugs Act* and the *Medical Devices Regulations.* Some devices, such as veterinary MEDICAL DEVICES, are subject only to the provisions of the Act. 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 *Medical Devices Regulations* do not require licences. Class I MEDICAL DEVICES are not subject to the device licence requirements of section 26.

The main flowchart in Appendix 2 guides readers in determining when they should use this document and which of the flowcharts provided in Appendices 3 and 4 is appropriate to their situation.

Flowchart A in Appendix 3 outlines the decision-making process for licensing MEDICAL DEVICES in general (excluding IVDDs). Flowchart B in Appendix 4 outlines the process for IVDDs.

Medical Devices (non-IVDDs)
The following is a question-and-answer discussion of each decision point of the Flowchart in Appendix 3: MEDICAL DEVICES that are not IVDDs.

Question A1: Is this a device SYSTEM?

Answer: A SYSTEM is a MEDICAL DEVICE composed of COMPONENTS. A device that is a single entity, for example an intra-ocular lens, is not a SYSTEM. In this case, the answer would be *NO*, which leads to question A2. If your response to question A1 is *YES*, refer to questions A1.1 and A1.2 to confirm that the device is a SYSTEM.

Question A1.1: Are all the COMPONENTS or parts sold under the SYSTEM name?

Answer: If the answer is YES proceed to A 1.2. If the COMPONENTS or parts are used in more than one SYSTEM and are not sold under the SYSTEM name, then the answer is NO, and the COMPONENTS can not be licensed as part of the SYSTEM.

Question A1.2: Are all the COMPONENTS labelled with the same MANUFACTURER'S name?

Answer: In order for the COMPONENTS to be licensed with the SYSTEM, they must be labelled with the same MANUFACTURER'S name and identified on the application by individual medical device names and IDENTIFIERS.

COMPONENTS that are made by another MANUFACTURER under a contractual arrangement can still be licensed with the SYSTEM, provided that the SYSTEM MANUFACTURER whose name appears on the label accepts responsibility for the quality systems requirements.

If the response to question A1.2 is *NO*, the COMPONENTS will have to be licensed separately by their MANUFACTURERS.

Example: The Total™ Phacoemulsification System manufactured by ABC Industries Inc. contains a number of COMPONENTS, including five interchangeable hand-pieces, up to fifteen models of coagulation accessories and numerous disposable supply packs. All but one of the above COMPONENTS are labelled with the head office address of ABC Industries, though the individual COMPONENTS may be manufactured at different branch manufacturing sites. One of the hand-pieces is made and labelled by a different MANUFACTURER. In regard to this COMPONENT, the answer to question A1.2 is *NO*, and the MANUFACTURER of the hand-piece will have to apply for a separate licence. The Total™ Phacoemulsification System, except for the above hand-piece, is the subject of one application, as a SYSTEM.

Question A2: Is this a MEDICAL DEVICE GROUP?

Answer: A medical device group refers to a medical device that is composed of a collection of medical devices, such as a procedure pack or tray, that is labelled and sold under a single name. If the answer to this question is *NO,* go to question A3. If the answer is *YES*, go to question A2.1.

Question A2.1: Can this device group be assigned to a MEDICAL DEVICE GROUP FAMILY?

Answer: A medical device group family refers to a collection of MEDICAL DEVICE GROUPS that are made by the same MANUFACTURER, have the same generic name specifying their INTENDED USE, and differ only in the number and combination of products that comprise each group.

If the answer to question A2.1 is *YES*, then the MANUFACTURER can apply using one licence application for the family, listing all possible device constituents, including bulk items. In this case, the MEDICAL DEVICE GROUP FAMILY name is considered the device name for this licence. This name must convey the INTENDED USE of the individual MEDICAL DEVICE GROUPS within the family.

Example: Pro-Pack Surgical Kits are manufactured by ABC Surgical Supply Company. These kits are MEDICAL DEVICE GROUPS containing a number of items including alcohol swabs, povidine-iodine sticks, gauze, sutures and needles, of varying size and shapes. Most of these items, though they are individually packaged and labelled, are bought in bulk from their MANUFACTURERS to be sold only as part of the kits.

ABC Surgical Supply Company may submit one 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 constituents are selected from a list of devices submitted with the group family licence application.

If the response to question A2.1 is *NO*, go to question A2.2.

Question A2.2: Are all of the constituent devices in the MEDICAL DEVICE GROUP made by the same MANUFACTURER?

Answer: If the answer is *YES*, then go to Question A2.3.

A *NO* response to A2.2 means that the MANUFACTURER should apply using one licence application for the MEDICAL DEVICE GROUP. The application must identify all the constituent devices of the group by device name.

Question A2.3: Have the constituent devices in the MEDICAL DEVICE GROUP already been licensed?

Answer: If the answer is *YES*, then the MEDICAL DEVICE GROUP is deemed licensed.

A *NO* response to question A2.3 means that the MANUFACTURER should apply using one licence application for the MEDICAL DEVICE GROUP. The application must identify all the constituent devices of the group by device name.

Example: The XYZ Vision Corporation wishes to provide a special promotional retail pack of their contact lens care products for the holiday season. Each of the constituent devices in this MEDICAL DEVICE GROUP is manufactured by XYZ Vision Corporation and is licensed for sale as a SINGLE MEDICAL DEVICE. Therefore the group is deemed licensed.

Question A2.4: Are any of the constituent devices of the MEDICAL DEVICE GROUP offered for sale individually?

Answer: If YES, then the MANUFACTURER of that constituent device must license it separately. Constituent devices are deemed licensed under the same licence application for the MEDICAL DEVICE GROUP only when they are sold, advertised or imported as part of the group.

Example: The IV Start Pack manufactured by Infusion Inc. contains various SINGLE MEDICAL DEVICES (needles, gauze bandages and alcohol swabs), conveniently packaged together for the purpose of starting an intravenous line. The MANUFACTURERS of the various constituent devices also offer these devices for sale individually. Therefore, Infusion Inc. can apply using one licence application for a MEDICAL DEVICE GROUP, but each device will also require a licence for each SINGLE MEDICAL DEVICE by the individual manufacturers.

Question A3: Is this a SINGLE MEDICAL DEVICE?

Answer: A SINGLE MEDICAL DEVICE can be identified by a unique device name for that MANUFACTURER and is sold as a distinct entity. The SINGLE MEDICAL DEVICE could be a COMPONENT not deemed licensed as part of a SYSTEM. This will be further discussed at question A3.3. If the answer is NO, the manufacturer is requested to contact the Programme for further guidance.

Question A3.1: Is this SINGLE MEDICAL DEVICE part of a MEDICAL DEVICE FAMILY?

Answer: A MEDICAL DEVICE FAMILY is composed of devices that are made by the same MANUFACTURER and that differ only in style, colour, flavour and/or size and have the same design, manufacturing process and INTENDED USE. A device family can be submitted as one licence application, which would contain the device names and associated catalogue detail of all constituent devices. The family can reflect only one overall purpose as per the definitions of INTENDED USE and INDICATIONS FOR USE.

If the response to A3.1 is *YES*, the reader should go to question A3.2.

Question A3.2: Is the MEDICAL DEVICE FAMILY licensed?

Answer: If the device family has been licensed, an amended licence application, specifying the device name and IDENTIFIERS, is required to add the new family member.

If the device family has not yet been licensed, the MANUFACTURER may apply using one licence application for a MEDICAL DEVICE FAMILY and making sure to provide the information described in Section 32 of the *Medical Devices Regulations*.

If the devices cannot be assigned to a MEDICAL DEVICE FAMILY, then a licence application is required for each individual MEDICAL DEVICE.

Example: The ABC™ Steerable Guidewire by Technologies Canada Ltd. is a MEDICAL DEVICE FAMILY available in a number of different sizes and styles, varying in length, tip shape and tip flexibility. However, products do not vary in material, and the range is consistent with a single INDICATION FOR USE. Therefore, this device can be licensed with a MEDICAL DEVICE FAMILY application, providing device IDENTIFIERS are supplied for the various size and style differences.

Question A3.3: Is this a COMPONENT for a SYSTEM produced by another MANUFACTURER?
Answer: If the answer to this question is *NO*, the MANUFACTURER is requested to contact the Therapeutic Products Programme for further guidance. If the response to this question is *YES*, the MANUFACTURER must submit a SINGLE MEDICAL DEVICE licence application for the COMPONENT.

Example: Software Solutions Inc. manufactures a software program, 3D Magic^{R} , which can be used with a number of CT scanners produced by other manufacturers. Although this device cannot function on its own, a licence is required and an application for a SINGLE MEDICAL DEVICE should be submitted.

In Vitro Diagnostic Devices

The following is a question-and-answer discussion of each decision point relating to the licensing of IVDDs. The Flowchart in Appendix 4 provides a diagram of these points.

Question B1: Is this an IVDD SYSTEM?

Answer: If the IVDD under consideration is composed of numerous COMPONENTS (e.g. collection devices, TEST KITS, automated ANALYZER), then it is a SYSTEM. Look at questions B1.1 and B1.2 to confirm that the IVDD does in fact conform to the definition of a SYSTEM.

If the IVDD is a single entity, such as a home TEST KIT for pregnancy, then the answer to question B1 is *NO*, and the reader should go to question B2.

Question B1.1: Are all the COMPONENTS sold under the SYSTEM name?

Answer: If the answer is *YES*, then the MANUFACTURER can apply to obtain a licence of a SYSTEM. However, when COMPONENTS are used in more than one SYSTEM and are not sold under the SYSTEM name, they can not be licensed with the IVDD SYSTEM.

Question B1.2: Are all the COMPONENTS labelled with the same MANUFACTURER name?

Answer: In order for the COMPONENTS in an IVDD SYSTEM to be licensed with the SYSTEM, they must be labelled with the same MANUFACTURER name. COMPONENTS that are made by another MANUFACTURER under a contractual arrangement can be licensed with the SYSTEM, provided that the MANUFACTURER whose name appears on the SYSTEM label accepts responsibility for the quality systems requirements.

In a device licence application for a SYSTEM, the MANUFACTURER is required to list the name and IDENTIFIERS of the analyzer and kit(s)/reagents(s).

For IVDD SYSTEMS that include TEST KITS, the reagents and articles of the TEST KITS are deemed licensed if they are labelled with the name of the TEST KIT's manufacturer (see question B2).This includes on-board reagents of ANALYZERS. Otherwise, an application for a SINGLE MEDICAL DEVICE must be submitted for each reagent or article made by another MANUFACTURER (see question B4)

If the response to question B1.2 is *NO*, the COMPONENTS or IVDD items will have to be licensed separately by their MANUFACTURERS.

Example I: The HLA Typing System is manufactured by ABO Industries Inc. This SYSTEM contains seven TEST KITS, each for the resolution of a different locus (DRB generic, DR1, DR2, DRB3, DR4, DR52, DRB5). The SYSTEM name appears on all components. All but one, the DRB generic kit, are labelled with the head office address of ABO Industries, though some reagents or articles of the TEST KITS may be manufactured at different branch manufacturing sites. The DRB generic kit is made and labelled by a different MANUFACTURER. In this case, the answer to question B1.1 is *NO*, and the DRB generic kit must be licensed separately (see question B2).

The HLA Typing System, not including the DRB generic TEST KIT, is the subject of one licence application as a SYSTEM. The device names and identifiers for all COMPONENTS must be provided as part of this licence application.

Example II: The INFECTION EIA random access ANALYZER (closed) and six TEST KITS (CMV, Rubella, Toxo-M, *Chlamydia*, HCV and HIV) are manufactured by XYZ Industries. As for most TEST KITS used with closed ANALYZERS, the system name and the MANUFACTURER'S name appear on all kits. An application for a Class IV licence submitted as a SYSTEM can be made for all TEST KITS and the ANALYZER or, alternatively, two licence applications can be submitted for two systems, one for the analyzer and the Class IV assays (HIV and HCV) and one for the analyzer and the Class III assays (CMV, Rubella, Toxo-M and *Chlamydia).* All reagents and articles of the kits are deemed licensed, provided they are labelled with the name of the TEST KIT MANUFACTURER (see question B2). Otherwise, these items must be individually licensed as single IVDDs (see question B4).

Question B2: Is this a TEST KIT?

Answer: This question seeks to determine if the IVDD under consideration is composed of numerous reagents or articles intended to be used together to conduct a specific test.

If the response to question B1 is *YES*, answering questions B1.1 and B1.2 will help to determine whether or not system or individual licenses are required for the reagents and articles.

Question B2.1: Are reagents or articles sold separately?

Answer: In cases where the answer is *NO*, it is assumed that the reagents or articles have been licenced with the TEST KIT. However, keeping in mind that the definition of TEST KIT does not preclude that some of the reagents or articles specifically required to perform the test may be sold individually, the answer to this question will often be *YES*, which leads to question B2.2. For example, a wash buffer concentrate may be sold separately from the remaining reagents and articles of the TEST KIT.

Question B2.2: Are the reagents or articles sold separately labelled with the same MANUFACTURER's name?

Answer: In order for the reagents or articles of a TEST KIT considered to be licensed under one licence application form for a TEST KIT, they must normally be labelled with the name of the TEST KIT MANUFACTURER. Some of the reagents or articles in the kit may be made by another MANUFACTURER, under a contractual arrangement. Provided the MANUFACTURER whose name appears on the TEST KIT label accepts responsibility for the quality systems requirements, these reagents or articles can be licensed with the TEST KIT.

If the response to question B2.2 is *NO*, the reagents or articles will have to be licensed separately by their MANUFACTURERS.

When applying for a licence that combines together reagents and articles into a TEST KIT , the MANUFACTURER is required to list all reagents and articles by device name and IDENTIFIERS.

Example I: The Bacteria EIA Test Kit is manufactured by XYZ Industries Inc. Numerous reagents and articles are required to perform this assay. Only one reagent, the wash concentrate, is sold individually. This reagent bears the name XYZ Industries on the label. Therefore, the answer to question B2.2 is *YES*, and the wash concentrate is deemed licensed as part of the TEST KIT.

Example II: The DRB generic TEST KIT that could not be licensed as part of the HLA Typing System manufactured by ABO Industries Inc.(See example I, question B1.4.) requires a TEST KIT licence.

Question B3: Is this a MEDICAL DEVICE GROUP?

Answer: The answer is yes if the group consists of devices sold together under one name, proceed to question B3.1. If the answer to this question is NO, go to question B4.

Questions B3.1: Are all of the constituent devices in the MEDICAL DEVICE GROUP made by the same MANUFACTURER?

Answer: If the answer is *YES*, then go to Question B3.2
IF the answer is *NO*, the application must identify all the constituent devices of the group by device name. The reader should then go to question B3.3

Question B3.2: Have the individual devices in the MEDICAL DEVICE GROUP already been licensed?

Answer: If the answer is *YES*, then the MEDICAL DEVICE GROUP is deemed licensed.

A *NO* response to question B3.2 means that the MANUFACTURER should apply using one licence application for the MEDICAL DEVICE GROUP. The application must identify all the constituent devices of the group by device name.

Example: The GLU Corporation wishes to provide a convenient pharmacy shelf pack consisting of the Better Glucose System (glucose meter, test strips, control solutions and linearity solutions) and the Sharp lancing device (with lancets). Each of the constituent devices in this MEDICAL DEVICE GROUP is manufactured by GLU Corporation and is already licensed for sale. Therefore the group is deemed licensed.

Question B3.3: Are any of the constituent devices of the MEDICAL DEVICE GROUP offered for sale individually?

Answer: If YES, then the MANUFACTURER of that constituent device must license it separately. Constituent devices are deemed licensed under the licence for the MEDICAL DEVICE GROUP only when they are sold, advertised or imported as part of the group.

Question B4: Is this a single IVDD?

A single IVDD can be identified by a unique name for that MANUFACTURER and is sold as a distinct entity. The single IVDD could be a reagent or article not deemed licensed as part of a SYSTEM or a TEST KIT. This will be further discussed at question B4.3. If the answer is NO, the manufacturer is requested to contact the Programme for further guidance.

Question B4.1: Is this IVDD part of a MEDICAL DEVICE FAMILY?

Answer: A MEDICAL DEVICE FAMILY is composed of devices that are made by the same MANUFACTURER and that differ only in style, colour, flavour and/or size and have the same design, manufacturing process and INTENDED USE. A device family can be submitted as one

licence application, which contain the device names and associated catalogue detail of all constituent devices. The family can reflect only one overall purpose as per the definitions of INTENDED USE and INDICATIONS FOR USE.

If the response to B4.1 is YES, the reader should go to question B4.2.

Question B4.2: Is the IVDD licenced as a MEDICAL DEVICE FAMILY?

Answer: If the medical device family has been licenced, an amended licence application, specifying the device name and IDENTIFIERS, is required to add the new family member.

If the device family has not yet been licenced, the MANUFACTURER may apply using one licence application for a MEDICAL DEVICE FAMILYand making sure to provide the information described in Section 32 of the *Medical Devices Regulations*.

If the devices cannot be assigned to a MEDICAL DEVICE FAMILY, then a licence application is required for each individual MEDICAL DEVICE.

Example I: The FUNGI™ Sensitivity disc, manufactured by ACME Inc., is a SINGLE MEDICAL DEVICE available in a number of different sizes, antibiotics and concentrations. The products do not vary significantly in manufacturing process and the use of different antibiotics is consistent with a single INDICATIONS FOR USE. Therefore, this IVDD can be licenced with a SINGLE MEDICAL device application, providing device IDENTIFIERS are supplied for the various size and style differences.

Question B4.3: Is this a reagent or article of a licenced TEST KIT or IVDD SYSTEM that is manufactured by the manufacturer identified on the licence?

Answer: If the answer to this question is YES, the articles or reagents are deemed licensed with the TEST KIT or SYSTEM. If the answer is NO, the MANUFACTURER must submit a SINGLE MEDICAL DEVICE licence application.

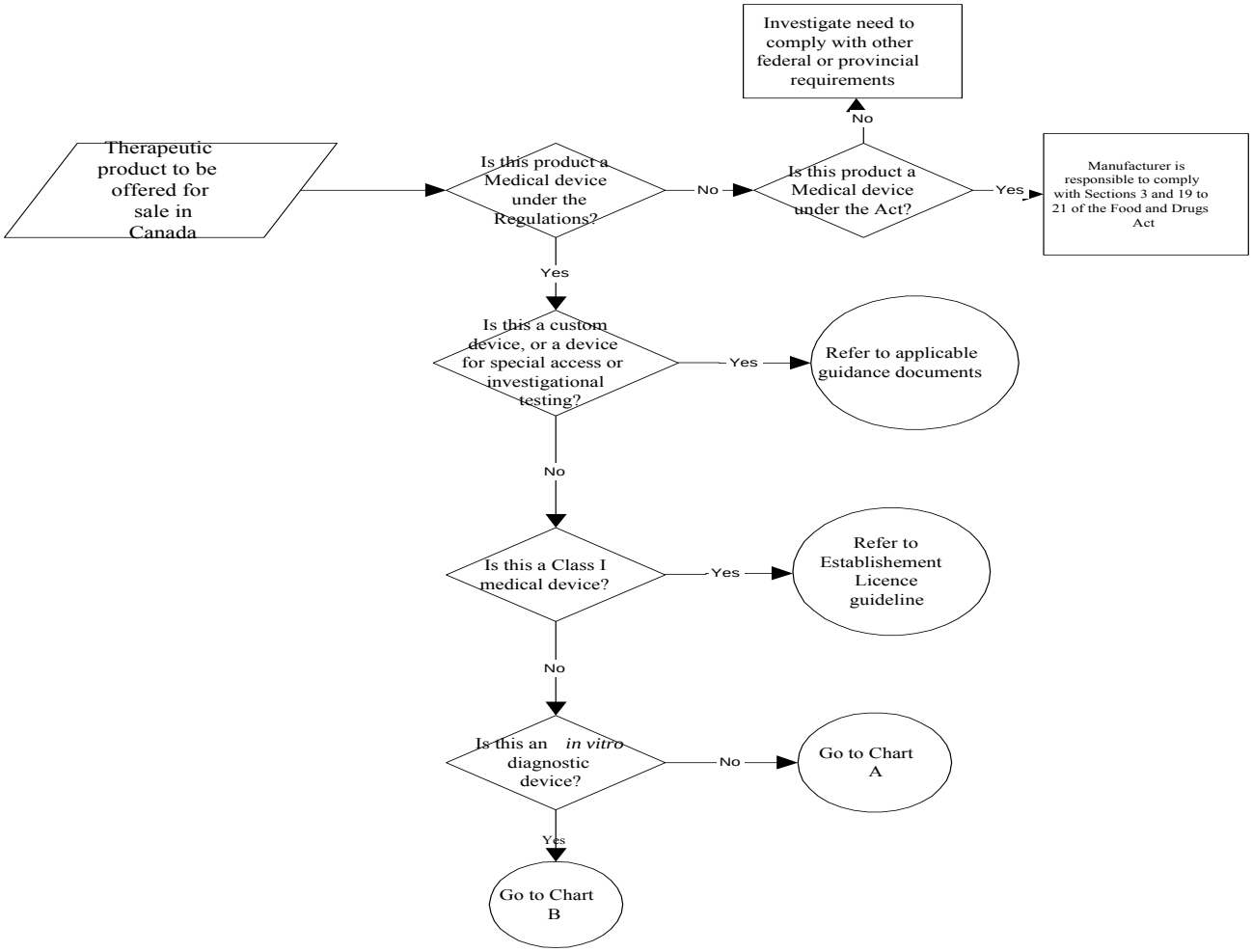
Example I: The ABC Electrolytes ANALYZER is a menu-driven, fully automated, non-expandable closed ANALYSER for the determination of electrolytes (Na^+, K^+, Ca^{++}, Cl^- and Li^+) from samples of urine, whole blood, plasma, serum or dialysate. One licence application is required for the ABC Electrolytes ANALYSER.

Example II: ABO Industries is developing a software program for the automation of another MANUFACTURER'S blood-screening assay on an open-ended ANALYSER in use in some blood centres. The assay itself has a valid licence with the Therapeutic Products Programme. An application as a SINGLE MEDICAL DEVICE is required for the software program.

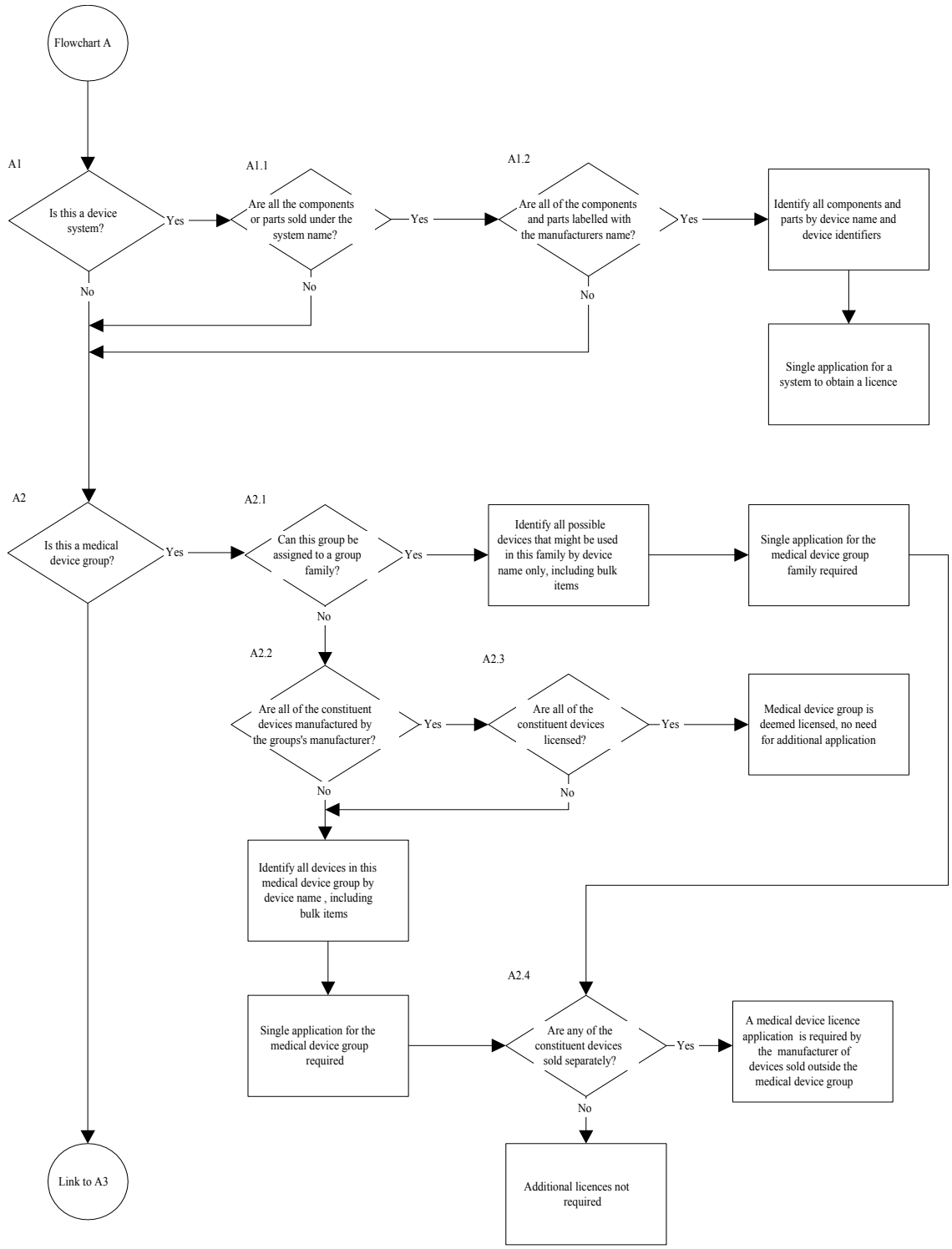
Question B5: Is this a reagent or article of a single IVDD, TEST KIT or IVDD SYSTEM made by another MANUFACTURER?

Answer: If the answer to this question is *NO*, the MANUFACTURER is requested to contact the Programme for further guidance. If the response to this question is *YES*, then the MANUFACTURER must submit a SINGLE MEDICAL DEVICE licence application.

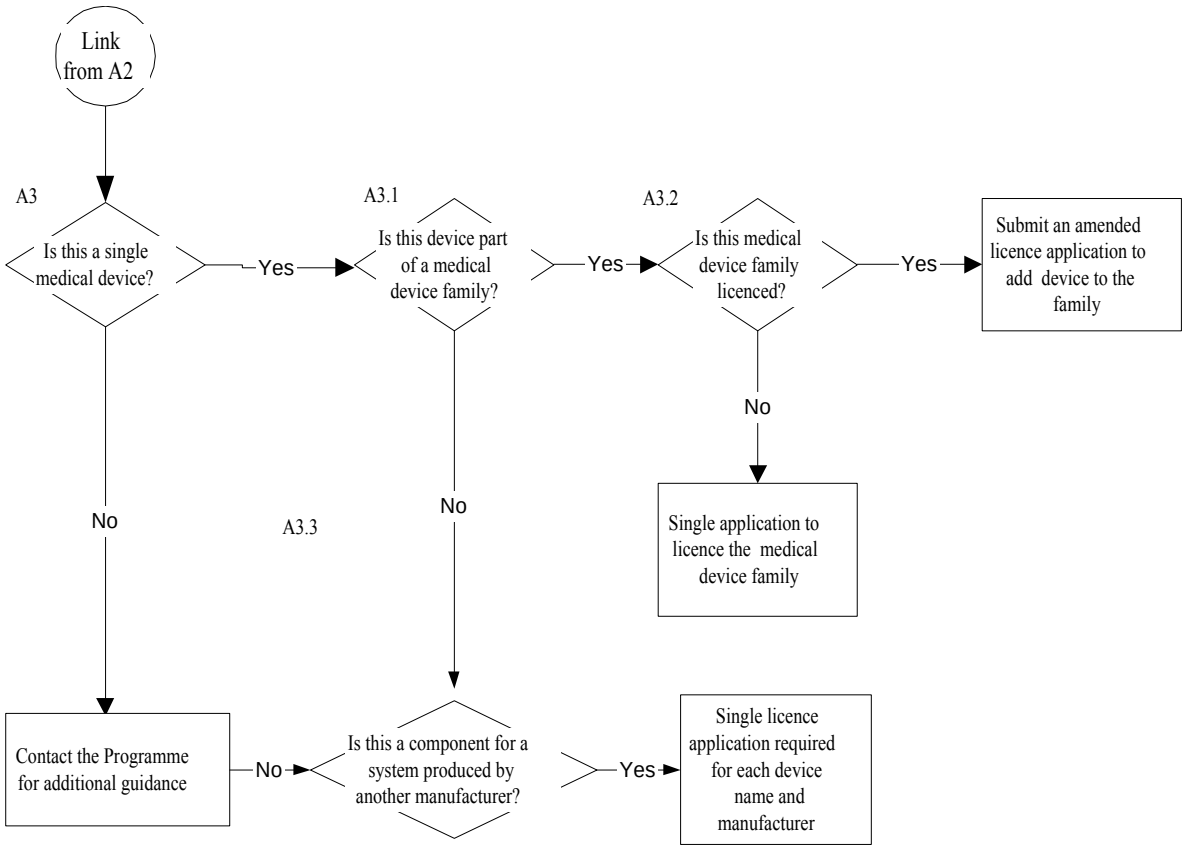
Appendix 2 - Main Flowchart



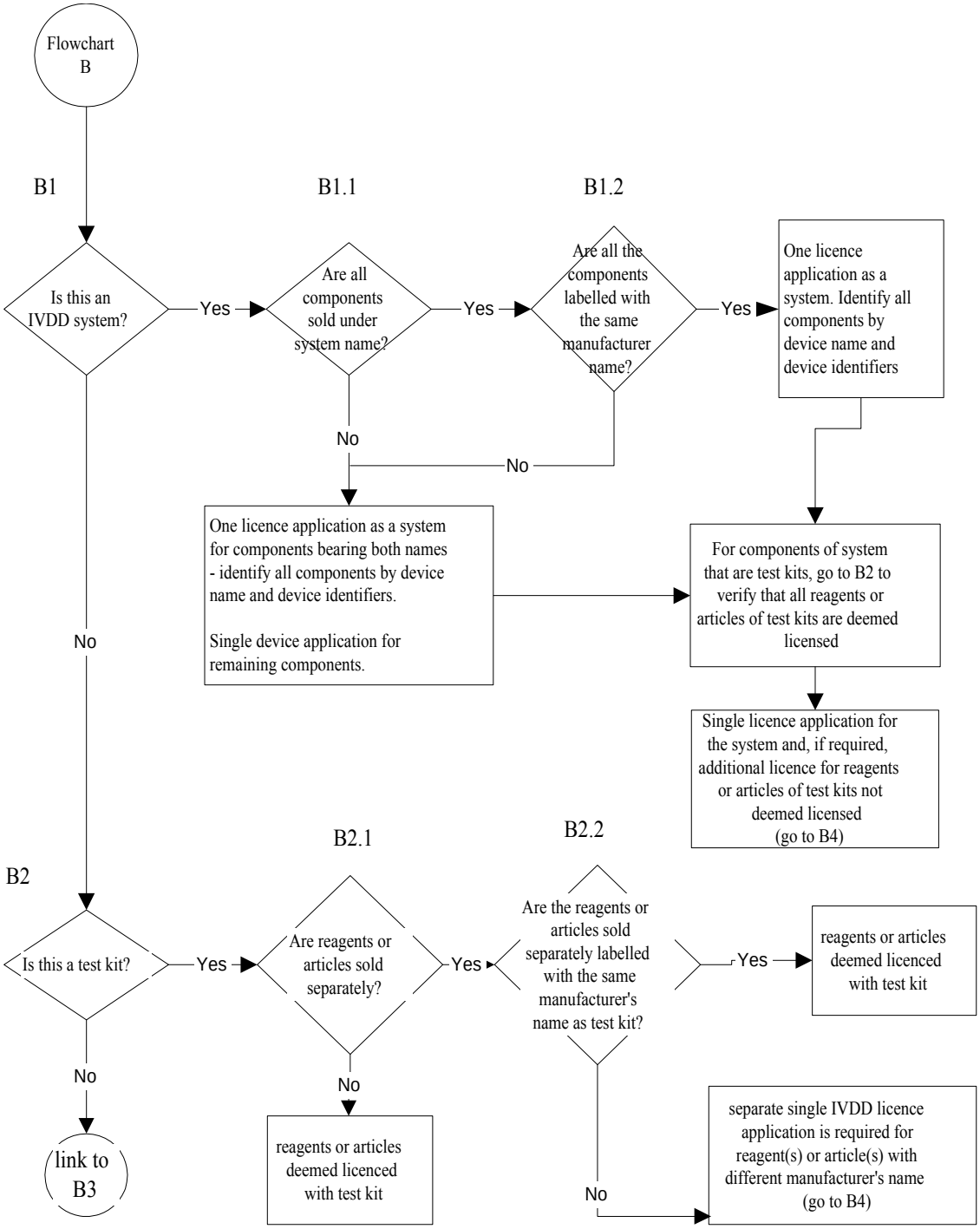
Appendix 3 - Flowchart - Medical Devices



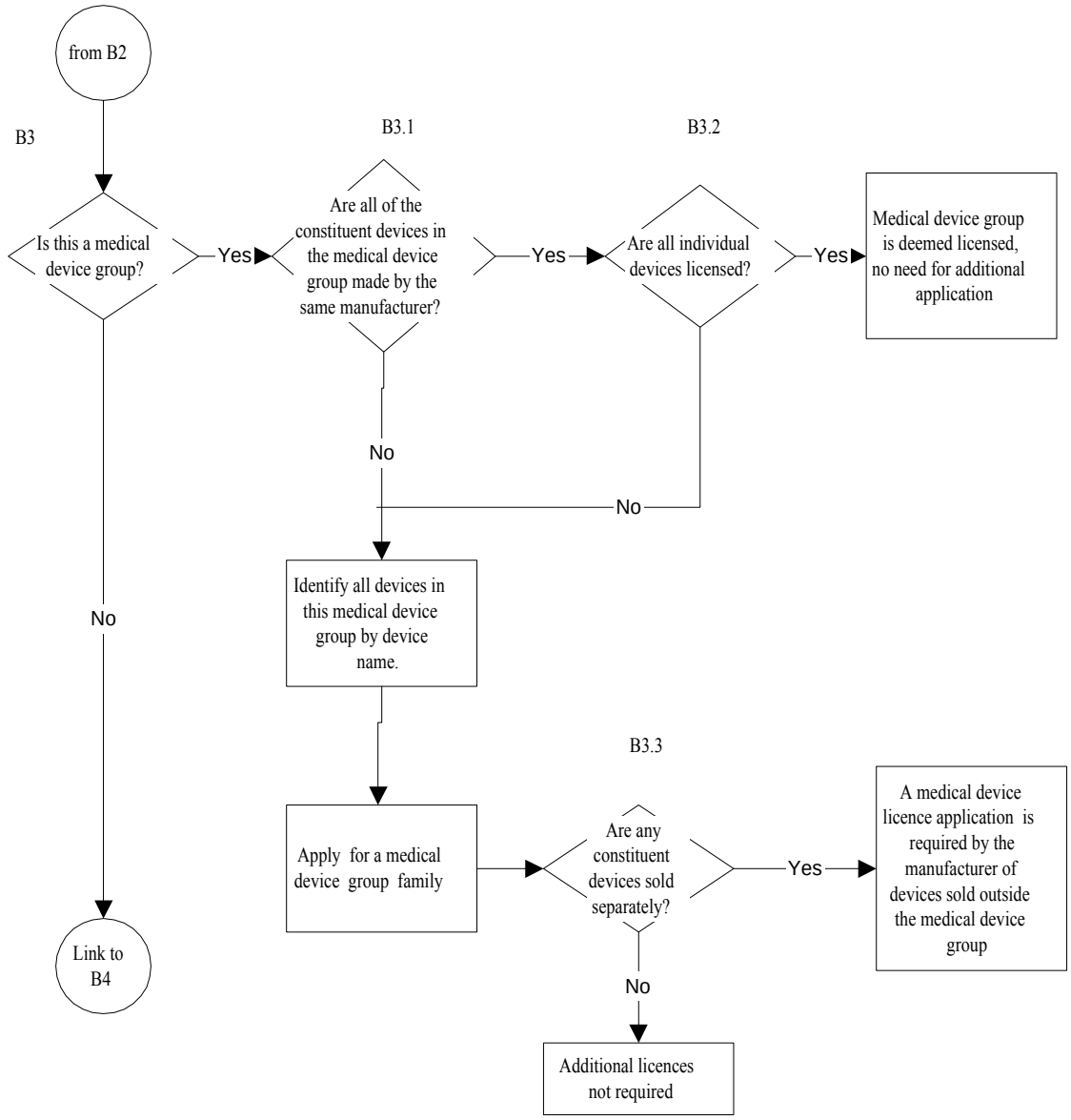
Appendix 3 - Flowchart A - Medical Devices (Continued)



Appendix 4 - Flowchart B -I*n Vitro* Diagnostic Devices



Appendix 4 - Flowchart B - *In Vitro* Diagnostic Devices (Continued)



Appendix 4 - Flowchart B - *In Vitro* Diagnostic Devices (Continued)