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GUIDANCE DOCUMENT

GD207: Guidance on the Content of ISO 13485 Quality Management System Certificates Issued by Health Canada Recognized Registrars

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Health Products and Food Branch

Canada 

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p>Health Canada</p>	<p>The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by:</p> <ul style="list-style-type: none"> • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. <p>Health Products and Food Branch</p>
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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches 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 a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1. INTRODUCTION

1.1 Purpose

The purpose of this document is to provide guidance to

- Manufacturers of Class II, III or IV devices; and,
- Health Canada recognized Registrars

on the essential information that Health Canada requires to be displayed on ISO 13485:2003 or ISO 13485:2016 quality management system (QMS) certificates.

1.2 Scope

The scope of this guidance document is limited to the essential information and format Health Canada requires displayed on a QMS certificate.

1.3 Supporting Documents

This guidance document contains undated references. In these cases, the following documents apply:

- (ISO 17021-1:2015) - Conformity assessment - Requirements for bodies providing audit and certification of management systems
- Food and Drugs Act (R.S., 1985, c. F-27) (<http://laws-lois.justice.gc.ca/eng/acts/f-27/>)
- Guidance Document - How to Complete the Application for a New Medical Device Licence
- Guidance for Industry - Private Label Medical Devices
- ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary
- ISO 13485:2003 (CAN/CSA- ISO 13485-03) Medical Devices - Quality management systems - Requirements for regulatory purposes
- ISO 13485:2016 (CAN/CSA- ISO 13485-16) Medical Devices - Quality management systems - Requirements for regulatory purposes
- ISO 15225:2016 Medical devices - Quality management - Medical device nomenclature data structure

- ISO 17011:2004 - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
- Medical Devices Regulations SOR/98-282 (latest consolidated version) (<http://laws.justice.gc.ca/eng/regulations/SOR-98-282/index.html>)
- Q90R0e : 2000-04-19, Policy on the Canadian Medical Devices Conformity Assessment System (CMDCAS)

1.4 Background

A Manufacturer will provide a valid certificate to Health Canada:

- to comply with sections 32(2)(f), 32(3)(j), 32(4)(p), and as applicable, 34 or 43.1 of the Medical Devices Regulations (MDR);
- as evidence of conformity with ISO 13485:2003 or ISO 13485:2016;
- as evidence of having documented and effectively implemented applicable sections of the MDR into their QMS; and,
- to indicate those devices that are designed and/or manufactured under the certified QMS.

ISO 17021-1:2015 states in the introduction, “The form of attestation of conformity of an organization’s management system to a specific management system standard or other normative requirements is usually a certification document or a certificate...The overall aim of certification is to give confidence to all parties that a management system fulfils specified requirements.”

Only valid certificates (see below) issued by Health Canada recognized Registrars will be accepted as objective evidence of compliance with sections 32(2)(f), 32(3)(j), 32(4)(p), 34 (in some cases), or 43.1 of the MDR. No other form of documentation will be accepted by Health Canada as a substitute (e.g., other certificates types, audit reports, letters, or attestations).

Despite this guidance, any certificate which contains ambiguous or conflicting information may be subject to a request for additional information or may be refused by Health Canada.

1.5 Quality Management System Standard

The MDR require the QMS under which Class II, III or IV medical devices are designed and/or manufactured satisfy the National Standard of Canada CAN/CSA-ISO 13485:03 or CAN/CSA-ISO 13485:16. There are no regulatory QMS requirements for Class I medical devices. Health Canada considers CAN/CSA-ISO 13485:03 and CAN/CSA-ISO 13485:16 to be equivalent to ISO 13485:2003 and ISO 13485:2016, respectively.

1.6 Class I Manufacturers, Importers, Distributors, and Private Labelling

Organizations that exclusively design, manufacture, and sell Class I medical devices for Canada shall not receive certification under the *Canadian Medical Devices Conformity Assessment System* (CMDCAS). However, Manufacturers of Class I devices that also design, manufacture and sell Class II, III or IV devices for the Canadian market are eligible for certification under CMDCAS and may voluntarily include Class I devices and other medical devices not sold in Canada in the audit process and in their QMS certificate scope statement.

The MDR do not require importers or distributors of medical devices to have a certified QMS. However, any importer or distributor of a Class II, III or IV device that chooses to become the Manufacturer by labelling and selling the device with their own name, trade-mark, design, trade name or other name or mark owned or controlled by them (see definition of a Manufacturer) shall comply with the QMS sections of the MDR and other applicable sections.

A Manufacturer who will obtain medical device licences *exclusively* through Health Canada's Private Label process is not required to obtain a QMS certificate. See Health Canada's website for additional details.

1.7 Revised Certificates

Revised certificates shall be valid and be based on any supplementary audit and approvals by the Health Canada recognized Registrar, as appropriate (ISO 17021-1:2015 9.6.4.1). Revised certificates will supersede and be clearly distinguished from any previously issued versions (ISO 17021-1:2015 8.2.2i)).

1.8 Terms, Definitions, Acronyms Accreditation

Third-party attestation related to a conformity assessment body (i.e., Registrar) conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO 17011:2004).

Certificate

For the purposes of this document, a CAN/CSA-ISO 13485:03 (or ISO 13485:2003) or CAN/CSA-ISO 13485:16 (or ISO 13485:2016) quality management system certification document, issued by a Health Canada recognized Registrar to be used by a Manufacturer for obtaining, maintaining, or amending a Health Canada medical device licence. Certificates issued by a CMDCAS recognized Registrar will bear the SCC's mark of accreditation.

CMDCAS

Canadian Medical Devices Conformity Assessment System

CMDCAS Recognized Register

Registrars that are recognized by Health Canada through the accreditation and sector qualification by the Standards Council of Canada (SCC). A list of CMDCAS recognized Registrars is on the Health Canada website.

Distributor

Any person, partnership, corporation, association, or other legal relationship which stands between the Manufacturer and the retail seller in purchases, consignments, or contracts for sale of consumer goods.

Generic Device Group

Refers to sets of devices having the same or similar intended uses or commonality of technology. (ISO 15225:2016)

Health Canada Recognized Register

Includes both CMDCAS recognized Registrars and Registrars that are directly recognized under section 32.1 of the MDR.

Importer

For the purposes of this document, an importer is a person, other than the Manufacturer of a medical device, who causes the medical device to be brought into Canada for sale.

ISO

International Organization for Standardization (www.iso.org)

Manufacturer

Means 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. (SOR/98-282)

MDR

Medical Devices Regulations (<http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/>)

Multi-Site (Organization)

A multi-site organization is defined as an organization having an identified central function (normally, and hereafter referred to as a central office) at which certain activities are planned, controlled or managed and a network of local offices or branches (sites) at which such activities are fully or partially carried out.

Private Label Manufacturer

Means a person who sells a private label medical device under their own name or trademark. (Guidance for Industry - Private Label Medical Devices)

Private Label Medical Device

Means a medical device that is identical in every respect to a medical device manufactured by an original Manufacturer and licensed by Health Canada, except that the device is labelled with the private label Manufacturer's name, address and product name and identifier. (Guidance for Industry - Private Label Medical Devices)

Quality Management System

Management system to direct and control an organization with regard to quality. (ISO 9000:2015).

Recognized Registrar

The Minister shall recognize a person as a Registrar for the purpose of issuing quality management system certificates if the person: (a) has sufficient training, experience and technical knowledge in the design and manufacture of medical devices and in the effective implementation of quality management systems to determine whether a quality management system satisfies a standard referred to in paragraph 32(2)(f), 3(j) or 4(p); and (b) conducts quality management system audits in accordance with the applicable guidelines and practices established by the International Organization for Standardization. (SOR/2003-173, s. 3; SOR/2006-197, s. 3)

Registrar

Organization that assesses and registers or certifies the quality management systems of Manufacturers with respect to published standards.

NB1: A Registrar may be called Certification Body (CB), Registration Body (RB) or Certification/Registration Body (CRB).

NB2: Conformity Assessment Body (CAB): body that performs conformity assessment services and that can be the object of accreditation (ISO 17011:2004 3.10)

SCC

Standards Council of Canada (www.scc.ca). The national accreditation body of Canada.

Valid Certification

A certificate indicating conformity to all certification requirements and all the content requirements as defined herewith.

2. CONTENT OF A CERTIFICATE

2.1 Unique Identification Code

The certificate shall bear a unique identification code (ISO 17021-1:2015 8.2.2d). The code is assigned by the Health Canada recognized Registrar to reference a unique certification/ registration or a unique certificate document. Either practice is acceptable provided that it is consistent and maintains adequate traceability for the users of the certificate.

Health Canada will use this code for administrative purposes. Registrars may choose a format that suits their operational needs, including embedding version control and other information in the code. However, the code is limited to 30 characters (without spaces).

2.2 Certificate Dates

Based on section 32.2 of the MDR, Health Canada requires two dates to be displayed on a certificate:

- effective date; and,
- expiry date *or* recertification due date.

Registrars may use a date format that suits their needs so long as it is unambiguous and consistent. To meet accreditation requirements (ISO 17021-1:2015 8.2.2b), other dates will be displayed, but they must not confuse the dates required by Health Canada.

2.2.1 *Effective Date*

Certificates shall bear an effective date. The field will be labelled “Effective date” and denote the commencement of the *certificate*’s validity period. The effective date shall *not* precede the date of the certification decision (ISO 17021-1:2015 8.2.2b).

Device licences, licence applications, and applications to amend the name or address on a licence must always be supported by a valid certificate. A certificate whose effective date occurs in the future (post-dated) is not in effect, for the purposes of licensing.

Consequently, a certificate received by Health Canada prior to the effective date will *not* be accepted.

Date of Certification Decision ≤ Effective Date ≤ Date Received by Health Canada

2.2.2 Expiry Date or Recertification Due Date

Certificates shall bear an expiry date *or* a recertification due date (ISO 17021-1:2015 8.2.2c) *or* both. The field(s) will be labelled “expiry” or “expiry date” or “recertification due date” and will denote the end of the certificate’s validity period.

2.2.3 Period of Validity

The period specified by the effective date and the expiry or the recertification due date shall not exceed three years (MDR section 32.2). If both expiry and recertification due dates appear on the certificate, the expiry date will be recorded by Health Canada.

2.3 Manufacturer’s Name

The certificate’s main page shall identify the name of the Manufacturer to whom the certification applies (ISO 17021-1:2015 8.2.2a). The Manufacturer’s name shall be the *same* as that used on the medical device licence and medical device label. An organization that 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 them is defined as the Manufacturer (MDR Section 1).

Health Canada will *not* accept certificates from a Manufacturer’s subcontractor as evidence of compliance to MDR sections 32(2)(f), 32(3)(j), 32(4)(p), 34, or 43.1.

Name on the Certificate = Name on the Licence = Name on the Device Label

Some organizations have a complex structure, with multiple names, sites, and ownership. However, the identified Manufacturer shall bear the responsibility of complying with the MDR.

In all situations, QMS documentation and certification agreements (ISO 17021-1:2015 5.1.2) between the entity(s) and the Health Canada recognized Registrar shall reflect the name(s) of the Manufacturer.

2.3.1 Business Units of a Parent Company

Health Canada will recognize a portion of a legal entity that is empowered to sign a device application, to be a legal entity for the purposes of obtaining a licence. Therefore, Registrars shall engage such entities, whether they be business units, subsidiaries, or divisions, as distinct legal entities for the purpose of certification under CMDCAS. The applicability of certificates issued to a division shall be limited to that division.

The name and address of parent companies or ownership groups may not appear on certificates, except where necessary to identify the legal name associated with the certified QMS. The following is an acceptable format:

ABC, a division of XYZ - a wholly owned subsidiary of 123 Address

or

Company ABC, Medical Device Division Address

2.3.2 Two or More Manufacturer's Names on a Certificate

In a situation where there is a *singly* defined QMS, associated with two or more names, the certificate may bear the additional names, subject to any verifications and/or certification requirements by the Registrar, including verifying the Manufacturer's intention to use all such names in Canada. The names will be listed in the following manner:

Company X
also trading as Company Y also trading as Company Z
...etc. Address

2.4 Manufacturer's Address

The certificate's main page, beneath the Manufacturer's name, shall identify the address to whom the certification applies (ISO 17021-1:2015 8.2.2a). The Manufacturer's address shall be the *same* as that used on the device licence and device label. A complete address would include a street name and number, city, province or state (where applicable), postal or zip code, and country. A post office box number may be added to the complete address.

Address on the Certificate = Address on the Licence = Address on the Device Label
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2.5 Multi-Site QMS

Manufacturers are required to define the scope (extent and boundaries) of the QMS in their quality manual (ISO 13485:2003, 4.2.2a or ISO 13485:2016, 4.2.2a). The scope generally includes a description of the physical locations, organizational units, and processes. If more than one physical location is defined within the scope of the QMS, i.e., a multi-site organization, then the names and street addresses of the branch offices shall also be listed and identified as additional sites on the certificate, provided they are covered by the certification (ISO 17021-1:2015 8.2.2a). Additional addresses shall not confuse the main address.

Where certificates display more than one scope statement (see below), Health Canada will record the “global” scope statement for regulatory purposes. The global scope statement shall adequately cover any “site-specific” scope statements and all generic device categories.

NB1: *Separate* entities, such as subcontractors, that provide product to the Manufacturer's specifications, are not under the direct control of the certified QMS and thus shall not be listed on the certificate.

NB2: Health Canada will *not* issue a device licence to a branch office. Only the Manufacturer, the “central office” of a multi-site, can obtain a licence.

2.6 Scope Statement

For regulatory purposes, the certificate’s scope statement consists of two components:

- QMS processes, including related services; and
- device listing.

It is incumbent upon the Manufacturer to draft the initial scope statement (ISO 17021-1:2015 9.2.1). The finalized scope statement will be subject to clarifications, audit findings, and the Registrar’s certification decision. (ISO 17021-1:2015 9.3.1.2.2d)

Manufacturers and Registrars are strongly encouraged to employ the scope templates found in Appendix 1.

2.6.1 QMS Processes, Including Related Services

A Manufacturer of a Class II device complies with MDR section 32(2)(f) by providing to Health Canada “a copy of the quality management system certificate certifying that the quality management system under which the device is **manufactured...**”. A Manufacturer of a Class III or IV device complies with MDR sections 32(3)(j) or 32(4)(p) respectively by providing to Health Canada “a copy of the quality management system certificate certifying that the quality management system under which the device is **designed and manufactured...**”.

Thus, depending on the class of the device(s) involved, the scope statement will contain “manufacture” or “design and manufacture”. A certificate which lacks “design” in the scope statement that is submitted in relation to a Class III or IV device will not be accepted by Health Canada. A certificate which lacks “manufacture” in the scope statement, regardless of the device class involved, will not be accepted by Health Canada (see notes below).

Additional QMS processes and services pertaining to the device may also be listed in the scope statement, but in most situations should be limited to QMS processes per ISO 13485:2003 (see ISO 13485:2003, 0.1) or 13485:2016 (see ISO 13485:2016, 0.1). All processes listed in the scope statement will be supported by evidence of conformity (ISO 17021-1:2015 9.3.1.3a). Any listed processes outside the scope of ISO 13485:2003 or ISO 13485:2016 shall be auditable and will have been carried out by audit teams possessing the necessary competence (ISO 17021-1:2015 7.2.7). Additional audit time will have been allocated and justified.

NB1: Health Canada will not accept “development” in place of “design”. “Design and development” is acceptable.

NB2: Health Canada considers manufacture and production to be interchangeable and thus use of either term is acceptable.

2.6.2 Device Listing

All medical devices that are:

- manufactured or designed and manufactured under an ISO 13485:2003 or ISO 13485:2016 QMS; and,
- licenced for sale or will be licenced for sale in Canada,

shall be listed in the certificate’s scope statement using *generic* device groups. Despite the use of generic device groups, the device descriptions shall be of sufficient detail such that there can be little to no reasonable doubt that the devices listed in the scope statement refer to the same device(s) in a licence application, renewal or amendment (the term “accessories” is not a generic device group). The templates in Appendix 1 cover a broad range of generic device groups. Other generic device groups may also be listed, such as Class I devices or devices that fall outside of the Food and Drugs Act definition but meet an ISO, or other national, or regional definition.

In addition to being accurate and complete, the scope statement should be robust; that is, it should not have to be modified every time devices are added or removed from the generic device groups covered by the scope, or that a design or manufacturing change is made to one of the specific devices included in the groups. Consequently, the listing of product names, trade names, catalogue numbers, device licence numbers, or device classes in the scope statement is not permitted. Certificates bearing such information will not be accepted by Health Canada.

Separate quality management system certificates for each component or member of a device family, group, group family, system and test kit will not be accepted by Health Canada.

2.7 Signing Authority

A certificate shall be signed by an officer who is employed and authorized by the Health Canada recognized Registrar to perform that function (ISO 17021-1:2015 5.1.3). The authorized person's name and position shall appear below or beside the signature.

2.8 Registrar's Name and Address

The Registrar's name and address shall appear on the certificate and shall be the same as that of the accredited entity (ISO 17021-1:2015 5.1.1) or the directly recognized entity (MDR section 32.1).

2.9 QMS Standard Audited Against

A certificate shall either reference CAN/CSA-ISO 13485:03 (or ISO 13485:2003) or CAN/CSA-ISO 13485:16 (or ISO 13485:2016). Additional references to other QMS standards or other normative documents are permitted (ISO 17021-1:2015 8.2.2e) but not recommended. Additional scope statements arising from other standards shall not detract from the information required by Health Canada (see 2.6).

2.10 Record of Registrar's Recognition

Registrars who are recognized by Health Canada through the accreditation and sector qualification process of the SCC shall make a claim on their certificates that they are CMDCAS recognized. The Registrar could use the phrase, "Canadian Medical Devices Conformity Assessment System recognized Registrar" or "CMDCAS recognized Registrar". The statement of CMDCAS recognition is restricted to certificates intended for current Class II, III, or IV licence holders or Manufacturers intending to obtain licences.

Registrars and Manufacturers shall *not* use any logos or symbols associated with the Canadian Federal Identity Program (http://www.tbs-sct.gc.ca/fip-pcim/index_e.asp) on their certificates (or other documentation).

2.11 Mark of Accreditation

CMDCAS recognized Registrars shall display the SCC's mark of accreditation (ISO 17021-1:2015 8.2.2g). Additional marks from other accreditation bodies may also be displayed, where

permitted. The use of such marks shall not be misleading and are subject to applicable laws, standards, agreements, etc.

Registrars that are *directly* recognized by Health Canada under section 32.1 of the MDR will not display the SCC's mark of accreditation.

2.12 Format

Manufacturers may be issued certificates in printed hard copy, faxed or electronic formats. For regulatory submissions, printed hard copy is the default format. Electronic format or fax submission is acceptable where Health Canada has specifically permitted or requested it.

Where a certificate exceeds one North American letter size (8.5 × 11") or ISO A4 (210 × 297mm) page, additional pages may be utilized, but shall display the Registrar's name or logo, and any appropriate traceability information such as the certificate's unique identification code and page numbers.

2.13 Language

As a minimum, the information Health Canada requires displayed on or attached to a certificate shall be in English or French. English-French bilingual format is acceptable. Although not recommended, information in languages other than English or French are permitted on the certificate. Multilingual certificates shall not confuse or contradict the essential information required by Health Canada.

APPENDIX 1: SCOPE STATEMENT TEMPLATES

The MDR, which applies to all products that meet the definition of a medical device that is found in the Food and Drugs Act (R.S., C. F-27, S.1), categorizes medical devices as either *in vitro* diagnostic devices or devices other than *in vitro* diagnostics. There is a template for each type.

- i) Determine if the product is an *in vitro* diagnostic device or not, as this will dictate which of the two “generic device group” templates to use. If a Manufacturer will licence both types of devices, then they may use both templates and formulate a hybrid scope statement.
- ii) Delete the QMS processes, generic device groups, and medical areas that do not apply.
- iii) The list of generic device group descriptions provided in each template is not comprehensive. Other generic device group descriptions can be added if the ones provided are not adequate. Health Canada’s Device Licensing Services Division may be contacted for assistance if a generic device group is not represented in the templates and a suitable one cannot be determined.

1. Template for *in vitro* Diagnostic Devices

The (design and development,) **manufacture**, (installation, service) **of** (in-vitro diagnostic analyzers/software, in-vitro diagnostic medical devices, in-vitro diagnostic reagents, in-vitro diagnostic test kits) **used in the** (diagnosis, management, detection) **of** (autoimmune status, blood analytes, blood components, blood gases, blood grouping, cancer, cardiac markers, coagulation, compatibility testing, disease status, donor screening, drugs of abuse, endocrine disorders, fertility testing, genetic testing, immune status, pregnancy testing, prenatal screening, protein metabolism, sexually transmissible agents, tissue typing, transmissible agents, immunological typing, therapeutic drug monitoring, other...) **including** (home use, near patient/point of care) **in-vitro diagnostic devices**.

2. Template for Devices other than *in vitro* Diagnostic Devices

The (design and development,) **manufacture**, (installation, service) **of** (anaesthesia systems, anaesthetic and/or breathing adaptors, biliary stents, bone prostheses, breathing circuits, cardiovascular stents, catheters, cochlear implants, computed tomography scanners, condoms, contact lenses, cryosurgical instruments, defibrillators, dental amalgams, dental implants, dental etchants, dermatological lasers, diagnostic ultrasound systems, dilatation catheters, disposable surgical instruments, ECG monitors, ECG leads, EEG recorder, elastomeric pumps, electrosurgical instruments and generators, endoscopes, examination gloves, guide wires, hearing aids, hemodialysis water purification systems, imaging and monitoring workstations, infusion

pumps, intraocular lenses, intravenous infusion sets, irrigation/drainage sets, mechanical and tissue heart valves, nebulizers, needles, ophthalmic lasers, orthopaedic implants, pacemakers, patient monitors, Picture Archiving Computer Systems (PACS), powered dental instruments, pulse generators, resorbable material implants, slit lamps, software, surgical gloves, surgical sponges, surgical lasers, surgical trays, sutures, syringes, therapeutic ultrasound devices, tonometers, vascular introducers, ventilators, wound dressings, x-ray equipment, other.....) **for the area of** (anaesthesiology, cardiovascular, dentistry, electrosurgical applications, ENT, gastroenterology, neurology, obstetrics and gynaecology, ophthalmology, orthopaedics, plastic surgery, radiology, urology).

APPENDIX 2: EXAMPLE SCOPE STATEMENTS

The following are examples of acceptable and unacceptable scopes statements for *in vitro* diagnostic devices.

Example A1

Manufacturer sells, or intends to sell, hand held chemistry and coagulation analysers.

Unacceptable Scope Statement

The development and commercialization of biosensor-based analytical systems.

Reason for Unacceptability

Design and manufacture are missing and the device description is too broad.

“Commercialization” refers to the management of a for-profit entity, which is too generic to be associated with a QMS process.

Acceptable Scope Statement

The design and development, manufacture, service of *in vitro* diagnostic cartridges, controls, analyzers/software, used in the diagnosis and management of blood analytes, blood components, and coagulation including near patient *in vitro* diagnostic devices.

Example A2

Manufacturer sells, or intends to sell, home pregnancy test kits and ovulation detection kits.

Unacceptable Scope Statement

The design and manufacture of IVDD's.

Reason for Unacceptability

The scope statement is too broad and ambiguous and does not specify the type of product or its intended use.

Acceptable Scope Statement

The design and manufacture of *in vitro* diagnostic test kits, used for the detection of pregnancy and ovulation including home use *in vitro* diagnostic devices.

Example A3

Manufacturer sells, or intends to sell, the following Class II devices: anti-GBM (Glomerular Basement Membrane), Antibodies (ELISA) kit, Anti-PR3 Antibodies (ELISA) kit (Serine Protease-3), HP-G Screen H Pylori (IgG) Antibodies (ELISA), MPO Antibodies (ELISA) kit (Myeloperoxidase).

Unacceptable Scope Statement

The design and development, and manufacture of Class II "We-Test-It" *in vitro* diagnostic kits, Canadian Licence #'s 134567, 134568, 134569, 134570, 134571 for the detection of infectious and autoimmune disease.

Reason for Unacceptability

Scope statement includes the class of device, its brand name, and Health Canada assigned licence numbers. The scope statement does not include immune response to food tests.

Acceptable Scope Statement

The design and development, and manufacture of *in vitro* diagnostic kits for the detection of infectious and autoimmune disease, including immune responses to food.

Example A4

The Manufacturer sells, or intends to sell, insulin dosers, lancets, lancing devices, consumer and hospital blood glucose monitoring systems, insulin delivery and blood glucose monitoring systems, control solutions, and test strips.

Unacceptable Scope Statement

Design and development, and manufacture of glucose monitors, test strips, and lancets.

Reason for Unacceptability

Scope statement does not cover all products presently licensed for sale in Canada or that are intended to be licensed for sale in Canada. Scope statement does not specify home and/or point of care use.

Acceptable Scope Statement

Design and development, manufacture and service of *in vitro* diagnostic devices used in the monitoring of blood glucose including lancets, lancing devices, control solutions and test strips including point of care and home use.

The following are examples of acceptable and unacceptable scopes statements for devices that are **not** *in vitro* diagnostic devices.

Example B1

Manufacturer sells, or intends to sell, synthetic surgical mesh, irrigation pumps, carbon dioxide pumps, electrosurgical electrodes, wound dressings, and infusion sets in Canada.

Unacceptable Scope Statement

The design and development and manufacture of electrosurgical electrodes, irrigation sets, infusion devices, and wound dressings.

Reason for Unacceptability

Scope statement does not cover synthetic surgical mesh or pumps

Acceptable Scope Statement

The design and development and manufacture of synthetic surgical mesh, powered irrigation sets, carbon dioxide and irrigation pumps, infusion sets, electrosurgical instruments, hemostatic and wound dressings.

Example B2

Manufacturer sells, or intends to sell, install and service ultrasound systems, probes, Picture Archiving Computer Systems (PACS), and workstations.

Unacceptable Scope Statement

Design and development, manufacture of ultrasound systems.

Reason for Unacceptability

Scope statement does not cover probes, Picture Archiving Computer Systems (PACS) or workstations.

Acceptable Scope Statement

Design and development, manufacture, installation and service of ultrasound systems, probes, Picture Archiving Computer Systems (PACS), and ultrasound workstations.

Example B3

Manufacturer sells, or intends to sell, sterile surgical gloves.

Unacceptable Scope Statement

The distribution of medical examination gloves.

Reason for Unacceptability

Scope statement does not include "manufacture" and uses incorrect generic device group "medical examination gloves" instead of "sterile surgical gloves".

Acceptable Scope Statement

The manufacture of sterile surgical gloves.

Example B4

Manufacturer is design responsible and sells, or intends to sell in Canada dental surface conditioners, dental cement, varnishes, restoration materials and implants.

Unacceptable Scope Statement

The manufacture of dental restoration materials.

Reason for Unacceptability

Scope does not indicate design and it does not include all generic device groups.

Acceptable Scope Statement

The design and development and manufacture of dental restoration materials, dental implants and materials for restoring and protecting teeth in the area of dentistry.