Health Canada Santé Canada

DRAFT GUIDANCE DOCUMENT

How to Complete the Application for a New Medical Device Licence

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	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: • 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. *Health Products and Food Branch*

Également disponible en français sous le titre : Ébauche de la ligne directrice - Comment remplir une nouvelle demande d'homologation pour un instrument médical

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

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 scientific 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 guidance, 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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Document Change Log			
File name		**Replaces**	md_gd_licapp_im_ld_demhom_e.wpd
Date		**Date**	2008/05/01

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Change	Location (section, paragraph)	Nature of and/or Reason for Change
1	Full Document	Rewritten to add clarity and conform to Good Guidance Practices.
2	Item 6	Removed reference to attestation of labelling requirements
3	Item 7	This section has been updated to indicate that the intended use statement on the application must be verbatim as it appears on the device labeling. It also requests a red lined and a clean electronic copy of the latest version of the IFU/PI be submitted with the application if there are any changes.
4	Item 11	The Radiation Emitting Medical Devices section has been added to provide manufacturers with more information about declaring a device that emits radiation.
5	Item 13	This section has been revised to provide Information on how to declare if your device contains nano-scale material.
6	Item 15	This section has been revised to include the requirement for a *Declaration of Conformity* form to accompany Class III and IV applications.
7	Item 16	Added reference to applicable guidance documents on labelling.

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1.0 INTRODUCTION

Medical devices are classified into one of four classes by means of classification rules, where Class I represents the lowest risk and Class IV represents the highest risk.

Class II, III and IV medical devices must be licenced prior to importation or sale in Canada.

A licence is issued to the device manufacturer for each application submitted, provided the requirements of the *Medical Devices Regulations* (MDR) are met.

1.1 Policy Objective

To provide information to manufacturers and regulatory correspondents on how to complete an application form for a new medical device licence.

1.2 Scope and Application

This guidance applies to all new Class II, III and IV medical devices.

1.3 Definitions

BISPHENOL A [BPA; Phenol, 4,4' -(1-methylethylidene)bis-] is an industrial raw material that was identified for screening assessment under the *Canadian Environmental Protection Act* (CEPA, 1999). BPA is primarily used as a raw material in the production of polycarbonates and epoxy resins. BPA or BPA-based polymers are used in the manufacture of a variety of medical devices, including resin-based dental composite restorative and prosthodontic materials, dental sealants, hemodialyzers, hemofilters and blood oxygenators. Please refer to Table 1 for the chemical identity of BPA, including its Chemical Abstracts Services (CAS) Registry Number and synonyms.

DEVICE ID refers to the device identification number assigned by Health Canada.

DI(2-ETHYLHEXYL)PHTHALATE (DEHP) is a chemical additive that is used to make polyvinyl chloride (PVC) soft, flexible and kink resistant. PVC plasticized with DEHP is currently used in a variety of medical devices, including blood bags, catheters, intravenous tubing and medical gloves. **A medical device shall be considered to contain DEHP if the amount of DEHP in the device is more than or equal to 0.1% of the device's mass [that is (i.e.), ≥0.1% w/w].** Please refer to Table 2 for the chemical identity of DEHP, including its Chemical Abstracts Services (CAS) Registry Number, synonyms and known trade names.

MEDICAL DEVICE means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

IDENTIFIER means 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. Examples of an identifier for a device are a catalogue, model or part number.

LICENCE APPLICATION TYPE means the application can be submitted either as a single device, a system, a test kit, a device group, a device family or a device group family. The term "test kit" applies only to *in vitro* diagnostic devices. For more information on licence application types, refer to the *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type*, which is available on the website.

MANUFACTURER means a person who sells the 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. "Person" includes a partnership, firm or association.

NEAR PATIENT *IN VITRO* DIAGNOSTIC DEVICE means an *in vitro* diagnostic device (IVDD) that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside.

2.0 GUIDANCE FOR IMPLEMENTATION

2.1 When is a New Medical Device Licence Required

Under the *MDR*, a new device licence is a pre-market requirement for:

a) any new device that was imported or sold in Canada after July 1, 1998;

b) a licensed device whose licence type is being modified from the type in the original licence application, as defined in the *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type*;

c) a device previously authorized for sale for investigational testing, or under the special access provisions of the *MDR*, that is now to be offered for general sale.

2.2 The Medical Device Licence Application Form

Device Classification

The rules to classify medical devices are outlined in Schedule 1 (Parts 1 and 2) of the *MDR*. Part 1 of Schedule 1 addresses medical devices other than *in vitro* diagnostics and Part 2 addresses *in vitro* diagnostic devices. For further guidance on the classification of medical devices, refer to the

documents *Guidance for the Risk-based Classification System*, or *Guidance for the Risk-based Classification System of In Vitro Diagnostic Devices*. **After ascertaining the class of the device, use the appropriate application form:**

***Draft* New Class II Medical Device Licence Application Form (**http://www.hc-sc.gc.ca/dhp-mps/consultation/md-im/licapp_demhom_cla2_draft_ebauche-eng.php);
New Class III Medical Device Licence Application Form (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/licapp_demhom_cla3-eng.php)**; or**
New Class IV Medical Device Licence Application Form (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/licapp_demhom_cla4-eng.php)

The document entitled *Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/keyword_motscles2-eng.php) is an alphabetical listing of all the short descriptors for devices that are entered into the Medical Devices System (MDS). The document contains synonyms and industry words that are commonly used to describe these devices, along with their respective classifications.

Item 1: NAME OF THE DEVICE (as it appears on the label)

The device name indicated for a system, medical device family or a medical device group family must appear, at least in part, on the label of each member device. Only one name is to be entered in Item 1. The device name on the application form will be used as the licence name unless the application is for a family of medical devices. In this case, a generic licence name that covers all possible trade names [for example (e.g.,) urinary catheters], should be indicated. The licence name usually reflects the types of devices that are contained within the licence and sometimes may vary from the device name.

Item 2: MANUFACTURER INFORMATION (as it appears on the label)

This is the name and address of the manufacturer of the device and the name and address to which the licence will be issued. A complete address must include: name and title of a contact person; Company ID (if known, this number is assigned by Health Canada); telephone number, Fax number and e-mail address of the contact person; street name and number or Post Office Box; city, province or state; postal or zip code; and country.

Item 3: REGULATORY CORRESPONDENT INFORMATION

All regulatory correspondence will be sent to this address (if different from Item 2), but the licence will be issued to the Manufacturer. A medical device licence application can be submitted by a third party; the mailing address and name of this authorized Regulatory Correspondent will be entered here.

Item 4: INVOICING INFORMATION

Enter the name, address and contact information of the party which will receive all invoicing and billing information; it may be the same as Item 2 or 3, or it may be a third party.

Item 5: QUALITY MANAGEMENT SYSTEM CERTIFICATE

Enter the certificate number and the name of the recognized registrar that has issued the certificate. A legible copy of the certificate must accompany each medical device licence application. For more information on the content and acceptance of quality management system certificates, refer to *GD207: Guidance on the content of ISO 13485 quality management system certificates issued by Health Canada recognized Registrars*. The certificate must be issued by a Health Canada recognized registrar. Refer to the Health Canada Web site for a current list of recognized registrars.

Item 6: ATTESTATIONS

Class II Licence Applications

Attestation of Compliance with the Applicable Requirements of sections 10 to 20

Manufacturers of Class II medical devices must attest that they have objective evidence establishing that they are compliant with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the *MDR*.

In the case of decorative contact lenses, manufacturers must attest that they have objective evidence establishing that they meet section 10, subsections 11(2) and 12(2) and sections 13 to 17 of the *MDR*.

Attestation of Investigational Testing for *in vitro* diagnostic devices (IVDDs)

Manufacturers of Class II near patient IVDDs must attest here that investigational testing of their device was conducted using human subjects representative of the intended patients and under conditions similar to the intended conditions of use of the device.

Near Patient Attestation

Manufacturers are to attest here that the device(s) is NOT a near patient IVDD.

Signature

The manufacturer of the device must sign and date the application.

Class III and IV Licence Applications

Attestation Section

Along with the application form, a manufacturer must submit the information requested in section 32, subsection (3) or (4) of the *MDR* is complete. Refer also to the document *Guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including In Vitro Diagnostic Devices (IVDDs)* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_data_im_ld_donnees_ciii_civ-eng.php) and *Guidance Document: Preparation of Summary Technical Documentation (STED)-based Class III and Class IV Premarket Medical Device Licence Applications, not including* In Vitro *Diagnostic Devices (IVDDs)* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_im_ld_sted-eng.php) and the *Guidance Document – Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications*.

Signature

The manufacturer of the device must sign and date the application.

Item 7: PURPOSE OR INTENDED USE OF DEVICE

Information provided for Item 7 is crucial to establishing the appropriate device class and should include the following:

- intended purpose, indications for use, conditions for which the device is used (the intended use statement should be verbatim as it appears on the device labelling);
- patient population for which the device is intended including age range, if applicable, and specific diagnoses;
- anatomical and physiological particulars related to the patient using the device, if applicable;
- whether or not the device uses an energy source and whether energy is transferred to the patient.
- the document, document version number and the date where the formal intended use appears.

Both a red lined and clean electronic copy of the latest version of the Information for Use/Package Insert (IFU/PI) should be submitted with the application if there are any changes.

Item 8: LICENCE APPLICATION TYPE

A manufacturer may apply for the following types of device licence:

A single medical device:

A single medical device is defined by a unique device name, is sold as a distinctly packaged entity and does not meet the criteria for a medical device group, a medical device family, a medical device group family, a system, or a test kit. It may be offered in a range of package sizes. Examples include: an acupuncture needle, an aneurysm clip, a larynx prosthesis or dental cement.

A medical device family:

A medical device family is 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. Examples include: intra vascular catheters, insulin syringes, feeding tubes or vascular access grafts.

A medical device group:

A medical device group is comprised of a collection of medical devices, such as a procedure pack or tray, that is sold under a single name. Examples include: a denture repair kit, a declotting tray, a parenteral administration kit or disposable circumcision tray.

A medical device group family:

A medical device group family is 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. Examples include: IV administration sets, dressing trays, contact lens care kits or irrigation trays.

System:

A system is 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 and are manufactured by the same manufacturer. Examples include hip prostheses, knee prostheses or an ultrasonic imaging system.

Test Kit:

A test kit is 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.

For further assistance in ascertaining the appropriate licence Application type for your product, consult the *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type*.

Item 9: PLACE OF USE

Indicate on the application form by checking the appropriate boxes.

Item 10: MEDICAL DEVICES CONTAINING DRUGS

Non-IVD Devices Containing Drugs

Do not complete this item if the device is an IVDD. If the device contains a drug or drug substance, ***which includes a pharmaceutical or biological drug, or a natural health product***, specify its brand or trade name, active ingredient(s), manufacturer, and its Drug Identification Number (DIN) or Natural Product Number (NPN). Health Canada's *Drug/Medical Device Combination Products Policy* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/combo_mixte_pol_2006-eng.php) addresses the regulation of products that are comprised of both a drug and a medical device.

IVDD Test Kits containing Controlled Substances

Please note that if the device is a test kit containing a substance listed in Schedule I, II, III or IV of the Controlled Drugs and Substances Act (CDSA), it would need to be registered with the Office of Controlled Substances. For information on how to apply for a Test Kit Number (T. K. Number), please refer to the Office of Controlled Substances Guidance Document entitled *Registration of a Test Kit for Medical, Laboratory, Industrial, Educational or Research Purposes* or contact the Office of Controlled Substances at (613) 952-2219 or (613) 957-1063.

Item 11: RADIATION EMITTING MEDICAL DEVICES

In this section, please indicate whether or not any of the devices contained in this application contain radiation emitting devices. A radiation emitting device is defined as any device that is capable of producing and emitting electromagnetic or acoustic radiation, and any component of or accessory to such a device.

Please note that if any of the devices listed on this application emit radiation, you may also be required to meet the requirements of the Radiation Emitting Devices (RED) Act. Please contact the Consumer and Clinical Radiation Protection Bureau to discuss these requirements at **ccrpb-pcrpcc@hc-sc.gc.ca** or **613-954-6699**.

Item 12: DEVICE HISTORY

Indicate if the device has been previously authorized for sale in Canada under the investigational testing or special access provisions of the *MDR*. If the device has been previously authorized for sale under the investigational testing provisions of the *MDR*, it will have a Device Identification (ID) number. If the device had been previously authorized for sale by the special access provisions of the *MDR,* it will have an Authorization number. The appropriate number must be supplied.

Item 13: IDENTIFIER OF DEVICE

Only devices, components, parts and accessories listed on the application will be considered for licensing. Spare parts that do not represent medical devices on their own should not be listed. If additional space is required, photocopy the Item 12 page and attach it to the application form.

For a **single device**, enter the name of the device in the first column and enter the identifier for the device (bar code, catalogue, model or part number) in the second column. If the device contains ≥0.1% by mass of DEHP, check the third column. If the device is manufactured from raw materials containing or derived from BPA, check the fourth column.

For a **medical device group**, a **medical device family**, or a **medical device group family**, the names of the constituent members must be listed in the first column. Associated identifiers must be entered in the second column. If a constituent member contains ≥0.1% by mass of DEHP, check the associated row in the third column. If a constituent member is manufactured from raw materials containing or derived from BPA, check the associated row in the fourth column.

Please refer to the *Policy Statement on Health Canada's Working Definition for Nanomaterial* found on the Health Canada website at http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php

Although the working definition indicates that a nanomaterial is a material within 1 to 100 nanometers in at least one dimension, for the purposes of medical device licensing, the Medical Devices Bureau is requesting notification for devices containing nano-scale materials with a particle size between 1 and 1000 nanometers.

Please identify the specific type of nano-scale material that is present in each device listed on the licence application. Examples of a specific type of nano-scale material could include nano titanium dioxide, nano silver, quantum dots, nano polymers, nano glasses, nano ceramics, carbon nanotubes and nano-fibres.

The last column is for Health Canada (HC) use only.

Refer to the definition of "BPA", "DEHP" and "identifier" in section 3 of this guidance document. **Please note that it is the manufacturer's responsibility to determine whether a medical device contains ≥ 0.1% w/w of DEHP or is manufactured from raw materials containing or derived from BPA.** The absence of a check mark in the third and fourth column in line with a specific device will be taken to indicate that the device does not contain ≥0.1% w/w of DEHP or is not manufactured from raw materials containing or derived from BPA.

Item 14: COMPATIBILITY OF INTERDEPENDENT DEVICES

For a device intended to be used with another Class II, III, or IV device, a list of all medical devices that this device is intended to be used or function with (including their licence number), is required. This is intended to be for system components from the same manufacturer.

An important requirement in demonstrating compliance with the applicable requirements of sections 10 to 20 of all medical devices intended to be used together is compliance with section 18 of the *MDR*. Section 18 requires that when medical devices are intended to be used with other medical devices, they must be compatible with every other medical device with which they interact, and don't adversely affect the performance of the combination of medical devices.

Failure to submit compatibility information for interdependent medical devices may lead to delays in the pre-market review of device licence applications while the Medical Devices Bureau requests the necessary information and manufacturers assemble and submit it for review.

Manufacturers are therefore reminded that the submission of evidence of compatibility for inter-dependent medical devices is a requirement under the *MDR*.

See also *Notice to Industry – Licensing Requirements of Interdependent Medical Devices (April 30, 2002)* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/notice_avis_syst_reqt_exig-eng.php).

Item 15: LIST OF RECOGNIZED STANDARDS COMPLIED WITH IN THE MANUFACTURE OF THE DEVICE

Refer to the documents on *Recognition and Use of Standards under the Medical Devices Regulations*. Health Canada uses these documents to identify standards that manufacturers may utilize in demonstrating that their devices comply with the applicable requirements of sections 10 to 20 of the *MDR*. Under Section 35 of the *MDR*, the Medical Devices Bureau may also request the manufacturer to provide additional evidence of compliance with the applicable requirements of sections 10 to 20. Note that standards not contained in the Policy may also be identified by manufacturers in support of the applicable requirements of sections 10 to 20. However, these standards should not be identified in item 15 of the application form. Instead, for a Class II medical device, they should be referenced by way of a letter accompanying the licence application, and for a Class III or IV medical device,

they should be listed in the information submitted to demonstrate compliance with the applicable requirements of sections 10 to 20.

For Class II licence applications, the manufacturer is to list the recognized standards complied with, or attest that they possess objective evidence that the device either meets an equivalent or better standard or has been tested and alternate evidence of compliance with the applicable requirements of sections 10 to 20 exists.

For Class III and IV licence applications, the manufacturer must respond "YES" where applicable and provide appropriate documentation:

- if the device conforms with recognized standards, the manufacturer must provide a *Declaration of Conformity* form indicating the standard(s);
- if the device does **not** conform with the listed recognized standards, but instead meets an equivalent or better standard, the manufacturer must provide a *Declaration of Conformity* form to indicate these equivalent or better standards; and
- if the device does **not** conform with the listed recognized standards **nor** meet an equivalent or better standard, the manufacturer shall include detailed information as evidence of compliance with the applicable requirements of sections 10 to 20.

If the manufacturer does not comply with any of these three options, a licence will not be issued.

Class II Licence Applications

Item 16: REVIEW DOCUMENTS

Indicate which review documents listed on the table are included as attachments to the application. For details regarding content and format of labelling material for Class II medical devices, consult Draft *Guidance for the Labelling of Medical Devices* and *Guidance for the Labelling of In Vitro Diagnostic Devices.*

Items 17 to 25: These items pertain to the payment of fees. Instructions are provided on the form itself. The instructions given for each item must be carefully followed to avoid delays in application processing. Consult also the *Guidance Document on Cost Recovery – Fees for the Review of Medical Device Licence Applications* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc_feesmd_docorient_fraisim-eng.php).

Class III Licence Applications

Item 16: REVIEW DOCUMENTS

Indicate which review documents listed on the table are included as attachments to the application. For details regarding content and format of review documents for Class III and IV medical devices, consult the *Guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including In Vitro Diagnostic Devices (IVDDs)* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_data_im_ld_donnees_ciii_civ-eng.php) and *Guidance Document: Preparation of Summary Technical Documentation (STED)-based Class III and Class IV Premarket Medical Device Licence Applications, not including* In Vitro *Diagnostic Devices (IVDDs)* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_im_ld_sted-eng.php).

Items 17 to 26: These items pertain to the payment of fees. Instructions are provided on the form itself. The instructions given for each item must be carefully followed to avoid delays in the processing of your application. Consult also the *Guidance Document on Cost Recovery – Fees for the Review of Medical Devices Regulations* (available on the website at http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc_feesmd_docorient_fraisim-eng.php).

Class IV Licence Applications

Item 16: REVIEW DOCUMENTS

Indicate which review documents listed on the table are included as attachments to your application. For details regarding content and format of review documents, consult the *Guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including In Vitro Diagnostic Devices (IVDDs)* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_data_im_ld_donnees_ciii_civ-eng.php) and *Guidance Document: Preparation of Summary Technical Documentation (STED)-based Class III and Class IV Premarket Medical Device Licence Applications, not including* In Vitro *Diagnostic Devices (IVDDs)* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_im_ld_sted-eng.php).

Item 17: DEVICES CONTAINING BIOLOGICAL MATERIAL

This section of the application form must be completed in detail. If additional space is required, photocopy the page and attach it to the application form.

Items 18 to 27: These items pertain to the payment of fees. Instructions are provided on the form itself. The instructions given for each item must be carefully followed to avoid delays in the processing of your application. Consult also the *Guidance Document on Cost Recovery - Recovery - Fees for the Review of Medical Device Licence Applications* (http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc_feesmd_docorient_fraisim-eng.php).

2.3 Before Submitting a Medical Device Licence Application

Before submitting a new medical device licence application, **ensure that**:

a) The device licence application form is complete. The manufacturer may choose to have a Regulatory Correspondent complete and submit the application on their behalf.

b) The manufacturer signs the application form, certifying that all the information in the application is accurate and complete. A faxed copy of the manufacturer's signature is acceptable.

c) The applicable licence fee for a Class II, III or IV medical device is submitted with the application.

d) The quality management system certificate is submitted with the application.

e) The Licence Application Disclosure Request is submitted with the application.

f) The manufacturer, or their Regulatory Correspondent, submits the application and any supporting documentation to:

Manager, Device Licensing Division, Medical Devices Bureau
Therapeutic Products Directorate
Health Canada
2934 Baseline Road. Tower B
Address Locator 3403A
Ottawa, Ontario
K1A 0K9

3.0 REFERENCES

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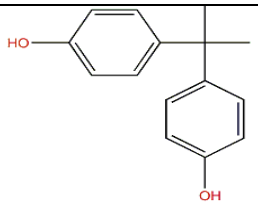
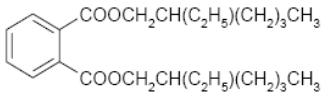
APPENDIX 1 – Table 1. Chemical Identity Of Bisphenol A

CHARACTERISTIC	INFORMATION
Chemical Abstracts Services (CAS) Registry Number	80-05-7
Domestic Substances List name	phenol, 4,4' -(1-methylethylidene)bis-
National Chemical Inventories (NCI) names[1]	phenol, 4,4'-(1-methylethylidene)bis- (TSCA, PICCS, ASIA-PAC) 4,4'-isopropylidenediphenol (EINECS, PICCS) 2,2-Bis(4'-hydroxyphenyl) propane (ENCS) phenol, 4,4'-(1-methylethylidene)bis- (AICS, PICCS) 4,4'-(1-Methylethylidene)bisphenol (ECL) 4,4'-Bisphenol A (ECL) phenol, 4,4'-(1-methylethylidene)bis- (SWISS) bisphenol A (SWISS, PICCS) p,p'-isopropylidene diphenol (PICCS) diphenol methylethylidene (PICCS) bis[phenol], 4,4'-(1-methylethylidene)- (PICCS) bisphenol-a (PICCS) bisphenol, 4,4'-(1-methylethylidene)- (PICCS) 4,4-isopropylidene diphenyl (PICCS) 4,4'-dihydroxyphenyl-2,2-propane (PICCS) 2,2-di(4-hydroxyphenyl)propane (PICCS) 2,2-di(4-hydroxyphenyl) propane (PICCS) 2,2-bis-(4-hydroxy-phenyl)-propane (PICCS)
Other names	bisphenol A diphenylolpropane BPA
Chemical group	Discrete organics
Chemical subgroup	Phenols
Chemical formula	$C_{15}H_{16}O_2$
Chemical structure	
SMILES	Oc(ccc(c1)C(c(ccc(O)c2)c2)(C)C)c1

[1] National Chemical Inventories (NCI). 2006: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists)_Toc173920654; ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Inventory of Newly Notified Substances and Giflist 1 - List of Toxic Substances) and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

APPENDIX 2 – Table 2. Chemical Identity of Di(2-Ethylhexyl)Phthalate

CHARACTERISTIC	INFORMATION	REFERENCE
Chemical name	di(2-ethylhexyl)phthalate	RTECS 2000
Synonyms	DEHP dioctylphthalate bis(2-ethylhexyl)phthalate	RTECS 2000
Registered trade names	Bisoflex 81 Eviplast 80 Octoil Plantinol DOP Staflex DOP	RTECS 2000
Chemical formula	$C_{24}H_{38}O_4$	RTECS 2000
Chemical structure		Howard and Meylan, 1997
Identification numbers: CAS Registry Number NIOSH RTECS EPA hazardous waste OHM/TADS DOT/UN/NA/IMCO shipping HSDB NCI	 117-81-7 TI0350000 U028 7216693 No data 334 C52733	 Cadogan and Howick, 1996 RTECS 2000 HSDB 1990 HSDB 1990 HSDB 1990 Montgomery and Welkom, 1990

CAS = Chemical Abstracts Services; DOT/UN/NA/IMCO = Department of Transportation/United Nations/North America/International Maritime Dangerous Goods Code; EPA = Environmental Protection Agency; HSDB = Hazardous Substances Data Bank; NCI = National Cancer Institute; NIOSH = National Institute for Occupational Safety and Health; OHM/TADS = Oil and Hazardous Materials/Technical Assistance Data System; RTECS = Registry of Toxic Effects of Chemical Substances.