

# NOTICE

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## **Release of the draft Guidance Document - Information to be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices**

Health Canada is pleased to announce the release of the draft *Guidance Document on Information to be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices* for a 60-day comment period.

The guidance document is intended to assist manufacturers in understanding and complying with the regulatory requirements of section 21(1)(i) of the *Medical Devices Regulations* as they pertain to the directions for use for reusable medical devices. This guidance document should be used in conjunction with the *Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations*.

**In order to provide industry with sufficient time to meet the specifications of the guidance document, Health Canada is contemplating a six-month transition period commencing on the date of implementation.** Following the transition period, Health Canada would expect manufacturers to meet the specifications listed in the guidance document in order to receive a medical device licence.

The draft document is available in both French and English on the Health Canada website at the following link: [http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

Comments on the draft guidance document and the proposed transition period should be submitted to Health Canada no later than **February 5, 2007** in order to allow sufficient time for their assessment.

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**DRAFT GUIDANCE DOCUMENT**  
Information to Be Provided by Manufacturers for the  
Reprocessing and Sterilization of Reusable Medical  
Devices

**This guidance document is being distributed for comment purposes only.**

Published by authority of the  
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**Health Products and Food Branch**

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health related to health products and food by:</p> <ul style="list-style-type: none"> <li>• minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,</li> <li>• promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.</li> </ul> <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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*Également disponible en français sous le titre :* Renseignements devant être fournis par les fabricants pour le retraitement et la stérilisation de matériels médicaux réutilisables

## 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 Policy Objective**

To reduce the risks associated with the use of reprocessed reusable medical devices by assisting manufacturers in providing detailed instructions to users for the effective disinfection, cleaning and sterilization of these devices, as required by section 21(1)(i) of the *Medical Devices Regulations*. (See Appendix I for text of section 21).

This guidance document should be used in conjunction with the *Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations*.

### **1.2 Policy Statement**

All manufacturers of reusable medical devices must include with their products appropriate reprocessing information that details the instructions for effective disinfection, cleaning and sterilization. This reprocessing information should meet the requirements of ISO 17664:2004 *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices* or the equivalent National Standard of Canada, CAN/CSA-ISO 17664:2004.

Alternately, as described in the *Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations*, the manufacturer may provide Health Canada with evidence showing that the instructions for reprocessing comply with another equivalent or better standard; or provide evidence that the instructions contain an equivalent level of detail to enable the user to effectively clean, disinfect and sterilize the product.

Manufacturers are also expected to meet the *Additional Expectations* section of this guidance document.

### **1.3 Scope and Application**

This guidance document applies to all manufacturers of Class I, II, III or IV reusable medical devices that are intended to be cleaned, disinfected or sterilized by the user.

## **1.4 Background**

Reusable medical devices are becoming increasingly complex and sophisticated as new technologies are developed. This increasing complexity often demands more challenging and arduous reprocessing of the devices prior to their reuse (reprocessing includes disinfection, cleaning and sterilization). Medical procedures involving inadequately reprocessed reusable medical devices carry the risk of exposing patients to pathogenic microbes which could lead to disease transmission from person to person.

Canadian health care facilities have expressed concerns that instructions provided with some reusable medical devices are not sufficiently detailed to enable users to reprocess these products effectively. The *Medical Devices Regulations* contain requirements for the labelling of products including directions for use (section 21(1)(i)). However, the *Medical Devices Regulations* do not specify any explicit requirements for the directions for use, such as their content and comprehensiveness.

In 2005, Health Canada referred this issue to the Health Canada Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD), composed of external experts in hospital infection control, reprocessing, sterilization, microbiology and standards development. The SAP-RMD reviewed the manufacturers' instructions provided with a variety of reusable medical devices and found that the quality and quantity of information provided was often inadequate. For example, some manufacturers had developed the practice of instructing users to follow routine hospital reprocessing procedures for the medical device rather than providing specific instructions for their products.

Following the review, the SAP-RMD recommended that Health Canada develop a guidance document to identify the reprocessing information that manufacturers should include in the instructions provided with their products, and that this information should comply with ISO 17664:2004 *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices* (ISO 17664:2004). The SAP-RMD also made some additional recommendations to help strengthen the quality of the instructions in an effort to further reduce the risks associated with the use of reprocessed reusable medical devices. Several of these recommendations have been included in this guidance document.

## **2 GUIDANCE FOR IMPLEMENTATION**

### **2.1 Guidance Document Application to Class I, II, III and IV Medical Devices**

This Guidance will be applied to Class I, II, III and IV reusable medical devices as described below.

#### ***2.1.1 Class I Medical Devices***

Class I medical devices are not subject to review and licensing by Health Canada. However, Class I medical devices must meet the general requirements of the *Medical Devices Regulations* including the labelling requirements described in Section 21. It is expected that manufacturers of Class I reusable medical devices will follow this guidance document in order to meet the labelling requirements, and will provide Health Canada with the necessary evidence to show compliance upon request.

#### ***2.1.2 Class II Medical Devices***

Under Section 32(2)(d) of the *Medical Devices Regulations*, a manufacturer applying for a licence for a Class II medical device must include an attestation by a senior official of the manufacturer that the device meets the applicable labelling requirements of the *Medical Devices Regulations*. It is expected that manufacturers of Class II reusable medical devices will follow this guidance document in order to meet the labelling requirements, and will provide Health Canada with the necessary evidence to show compliance upon request.

#### ***2.1.3 Class III and IV Medical Devices***

Under Sections 32(3)(g) and 32(4)(o) of the *Medical Devices Regulations*, a manufacturer applying for a licence for a Class III or IV medical device must include with the application a copy of the medical device label and the directions for use. In complying with these regulatory requirements, manufacturers should submit to Health Canada evidence that the directions for use provided with the reusable medical device meet the specifications of this guidance document.

If a manufacturer elects to demonstrate conformance with ISO 17664:2004 or CAN/CSA-ISO 17664:2004, a *Declaration of Conformity* must be submitted in accordance with section 2.1.2 of the *Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations*. If a manufacturer elects

- to comply with an equivalent or better standard; or
- to provide alternate evidence that the instructions contain an equivalent level of detail to enable the user to effectively reprocess the product,

the manufacturer must provide Health Canada with detailed information with the medical device licence application. If the manufacturer does none of the above, a licence will not be issued.

## 2.2 ISO 17664:2004

ISO 17664, developed by the International Organization for Standardization, specifies the information to be provided by a medical device manufacturer on the reprocessing of medical devices claimed to be resterilizable and medical devices intended to be sterilized by the reprocessor. The purpose of ISO 17664 is to ensure that the reprocessing instructions included with the device provide sufficient clear information so that the medical device can be reprocessed safely and will continue to meet its performance specification. The standard includes requirements for reprocessing, including:

- preparation at point of use;
- preparation, cleaning, disinfection;
- drying;
- inspection, maintenance and testing;
- packaging;
- sterilization;
- and storage.

The standard also provides templates for the presentation of this information.

## 2.3 Additional Expectations

### 2.3.1 General

All information provided to the purchaser of the medical device, either by the manufacturer, importer or authorised dealer, should be endorsed by the manufacturer.

### **2.3.2 Information to be provided upon request by the purchaser**

Upon request by the purchaser of the medical device, the manufacturer or importer should provide the following information:

- a) The names of suppliers of equipment, tools, cleaning agents, disinfectants, sterilants or other products suitable for use in reprocessing and testing of the medical device.
- b) Validation data that confirms that the specific medical device in question will be clean and sterile when reprocessed as directed.
- c) Validation data for sterilizing the medical device while in its container, if the medical device is sold in a container in which it is to be sterilized.

### **2.3.3 Instructions**

- a) Instructions for disassembly and reassembly of the medical device should include photographs or schematic diagrams and a list of the components of the medical device.
- b) Instructions should include test methods for verifying the functionality and safety of the medical device, as required.
- c) Instructions should be specific to the medical device in question. An identifier, such as a catalogue number, should be provided in the instructions and marked on the medical device.
- d) Reprocessing instructions should specify the process temperatures and times to be used.
- e) Reprocessing instructions should take into account the equipment likely to be available to the reprocessor and the times and temperatures commonly used.

### **2.3.4 Limited Use Devices**

A reusable medical device designated by the manufacturer as intended for a limited number of reprocessing cycles should be marked with an identifier unique to that individual medical device which enables the user to:

- a) track the number of times the medical device has been reprocessed; or
- b) identify when the medical device will no longer safely fulfil its intended use.

## **APPENDIX I - Labelling Requirements of the *Medical Devices Regulations***

21. (1) No person shall import or sell a medical device unless the device has a label that sets out the following information:
- a) the name of the device;
  - b) the name and address of the manufacturer;
  - c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
  - d) in the case of a Class III or IV device, the control number;
  - e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;
  - f) the word “Sterile”, if the manufacturer intends the device to be sold in a sterile condition;
  - g) the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;
  - h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use;
  - i) the directions for use, unless directions are not required for the device to be used safely and effectively; and
  - j) any special storage conditions applicable to the device.
- (2) The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.