Notice: Classification and Licensing of High-Level Disinfectants and Sterilants as Medical Devices

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Effective March 16, 2018, high-level disinfectant and sterilant solutions (including contact lens disinfectants) [1] intended for use on medical devices are classified by Health Canada as medical devices. Medical device disinfectants and sterilants that **do not meet** the definition of an antimicrobial agent in the Food and Drug Regulations (FDR) [2] are no longer regulated under the FDR and are now subject to the requirements of the Medical Devices Regulations (MDR.) Disinfectants that meet the definition of an antimicrobial agent continue to be regulated as drugs and subject to the requirements of the FDR.

The reclassification of high-level disinfectant and sterilant solutions from drugs to medical devices is an initiative under the Canada-United States Regulatory Cooperation Council (RCC) Work Plan for Medical Devices. RCC initiatives are intended to better align the regulatory requirements of Canada and the United States.

At this time, these products are considered to be Class II medical devices, in accordance with Schedule 1, Part 1, Rule 13(b) of the Medical Devices Regulations. However, to better align the device risk classification with the nature and intended use of these products, Health Canada intends to pursue an amendment to the MDR that would reclassify these products as Class III medical devices.

Health Canada is allowing an 18 month transition period from the date of this publication for manufacturers of market authorized disinfectants and sterilants to obtain quality management system (QMS) certificates. Further information on how to obtain a QMS certificate is available on the Health Canada website.

The following sections list the respective licensing requirements for medical device disinfectant and sterilant solutions that either are currently authorized for market or require new licence applications.

1. Medical device licensing of market authorized disinfectant and sterilant solutions:

Manufacturers of high-level disinfectants and sterilants that have already received market authorization as drugs (i.e., have received a Drug Identification Number or DIN) will need to complete and submit an application for a Class II Medical Device Licence, including:

- a Quality Management System Certificate;
- a device label in compliance with the MDR; and
- the fee for the Class II device licence application.

For an accessible version of the form please call 613-957-7285.

In addition, manufacturers will need to provide the existing DIN (section 16 of the Class II Medical Device Licence form), which will confirm safety and effectiveness compliance as per the Safety and Effectiveness Requirements for Contact Lens Disinfectants (2018), or the Safety and Effectiveness Requirements for High-Level Disinfectants and Sterilants for use on Reusable Semi-Critical and Critical Medical Devices (2018) guidance documents.

From the date of this Notice, manufacturers will be granted an 18 month transition interval to obtain a medical device licence, during which their authorized products will be allowed to remain on the market**.**

2. Medical Device licensing of new disinfectant and sterilant solutions as medical devices:

Effective March 16, 2018, all new applications for market authorization of disinfectant and sterilant solutions intended for use on medical devices will be subject to the medical device regulatory pathway. For devices imported or sold in Canada, manufacturers will be required to complete an Application for a Class II Medical Device Licence, including:

- a Quality Management System Certificate ;
- a device label in compliance with the MDR; and
- the fee for the Class II device licence application.

For an accessible version of the form please call 613-957-7285.

In addition, manufacturers will need to provide information to Health Canada to demonstrate that the disinfectant or sterilant solution meets sections 10-20 of the MDR. An attestation will not be accepted. Information on these requirements is available in the guidance documents on Safety and Effectiveness Requirements for Contact Lens Disinfectants (2018), and Safety and Effectiveness Requirements for High-Level Disinfectants and Sterilants for use on Reusable Semi-Critical and Critical Medical Devices (2018).

Instructions on how to file a medical device licence application in the electronic format are described in the guidance document on Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" Format. Manufacturers should use the Medical Device Class III Device Licence Application format to submit this information.

Questions or concerns regarding this notice should be directed to Policy_Bureau_Enquiries@hc-sc.gc.ca. For questions on medical device licensing, please contact mdb_enquiries@hc-sc.gc.ca.

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1 Health Canada defines “high-level disinfectant” and “sterilant” as follows:

- A high-level disinfectant is a substance, or mixture of substances, capable of destroying or irreversibly inactivating all microbial pathogens, but not necessarily large numbers of bacterial spores.
- A sterilant is a substance, or mixture of substances, capable of destroying or irreversibly inactivating all forms of microbial life present on inanimate objects, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses, present on inanimate objects.

2 Section C.01A.001(1) of the Food and Drug Regulations define “antimicrobial agent” as “a drug that is capable of destroying pathogenic micro-organisms and that is labelled as being for use in the disinfection of environmental surfaces or medical devices, as defined in the Medical Devices Regulations, that

a. are not invasive devices as defined in those Regulations; and
b. are intended to come into contact with intact skin only.”

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