Reclassification of High-Level Disinfectant and Sterilant Solutions

OVERVIEW

On March 16, 2018, Health Canada announced that high-level disinfectant and Sterilant Solutions that are intended for use on medical devices have been reclassified as Class II medical devices as of March 16, 2018. These will be regulated under the Medical Device Regulations (MDR) rather than the Food and Drug Regulations (FDR).

WHO DOES THIS APPLY TO?

▪ All manufacturers, importers, and distributors that currently hold a Drug Establishment Licence (DIN) for a high-level disinfectant and/or sterilant solution (including contact lens disinfectants) intended to be used on medical devices
▪ Distributors located outside Canada who are selling to Canadian Facilities

KEY POINTS

▪ High-level disinfectant¹ and sterilant solutions have changed from a drug to a “Class II medical device,” in accordance with Schedule 1, Part 1, Rule 13(b) of the MDR
▪ Disinfectant products that meet the definition of an antimicrobial agent will continue to be regulated as drugs and must meet the food and drug regulations
▪ Companies with drug products that apply have a transition period of 18 months to obtain ISO quality management system (QMS) certificates and a Health Canada Medical Device license (MDEL)
▪ The 18-month transition interval from the date of notice (March 16, 2018) will be September 2019 if adhered to (Health Canada has not assigned an end date)
▪ Health Canada is proposing to amend the MDR to further reclassify these products as Class III medical devices, a stricter classification. No timeline has been assigned to this proposed change
▪ New product submissions for high-level disinfectants and/or sterilants have to meet Class III medical device requirements

¹ See Definitions for what qualifies as a ‘high-level disinfectant’
WHAT DO I NEED TO DO?

For market authorized disinfectant and sterilant solutions that already have a DIN:

1. Complete and submit an application for a new Class II Medical Device Licence, including a:
   a. QMS Certificate
   b. Device label compliant with the MDR
   c. Application fee

2. Provide the existing DIN (section 16 of the Class II Medical Device Licence form), to confirm safety and effectiveness compliance as per:
   a. Safety and Effectiveness Requirements for Contact Lens Disinfectants (2018), if applicable
   b. Safety and Effectiveness Requirements for High-Level Disinfectants and Sterilants for use on Reusable Semi-Critical and Critical Medical Devices (2018)

For new disinfectant and sterilant solutions to be imported or sold in Canada as medical devices as of March 16, 2018 (i.e., no DIN):

1. Complete an application for a new Class II Medical Device Licence, including:
   a. Information that the disinfectant or sterilant solution meets sections 10-20 of the MDR
   b. QMS Certificate
   c. Device label compliant with the MDR
   d. Application fee
DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>DIN</td>
<td>Drug Identification Number</td>
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<tr>
<td>FDR</td>
<td>Food and Drug Regulations</td>
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<tr>
<td>High-level Disinfectant</td>
<td>A substance, or mixture of substances, capable of destroying or irreversibly inactivating all microbial pathogens, but not necessarily large numbers of bacterial spores</td>
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<tr>
<td>MDEL</td>
<td>Medical Device Licence</td>
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<tr>
<td>MDR</td>
<td>Medical Device Regulations</td>
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<tr>
<td>Medical Device</td>
<td>Health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.</td>
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<tr>
<td>Sterilant</td>
<td>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.</td>
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RELATED DOCUMENTS

Medical Device Regulations
General Information for Medical Devices
Medical Devices Guidance Documents
Guidance Document for the High Level Disinfectants and Sterilants
FAQ

1. **How do I file a Medical License Application?**

   Apply electronically [Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" Form](#).

2. **How long do I have before the reclassification is effective?**

   The reclassification is effective now ([Date of Notice: March 16, 2018](#)); however, Health Canada is allowing an 18-month transition interval from the date of the notice for industry to obtain the relevant documentation. This will be September 2019 if adhered to (Health Canada has not specified an end date).

3. **Can I still import and distribute my product?**

   Yes; however, you will be required to obtain the relevant documentation prior to end of the 18-month transition period.

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