



POMDRA
Update

[Useful guidance on medical device reprocessing in community-based practice \[1\]](#)

The following are common questions from physicians with guidance on addressing the concerns.

How do community-based physicians know if the tabletop steam sterilizer they are currently using, or are considering purchasing, is both approved for use in Canada, and appropriate for use in an office-based setting?

Physicians should be aware that there are three key requirements that the sterilizer must have:

1. Health Canada approval and classification: Any sterilizer sold in Canada **must** be approved and classified by Health Canada otherwise it cannot be used in Canada. To be sure,
 - ask the medical supplier to verify that the sterilizer is validated by Health Canada, or
 - if the sterilizer is used and/or purchased online, enter the sterilizer make and model in the Government of Canada's [Medical Devices Active Licence Listing \[2\]](#).
2. Canadian Standard Association (CSA) electrical safety inspection sticker: Any sterilizer sold in Canada must pass the CSA electrical safety requirements.
 - Look for CSA or Underwriters' Laboratories (UL) electrical safety inspection

sticker on the sterilizer.

3. Manufacturer's instructions indicate that sterilizer can reprocess packaged and lumened/cannulated medical devices. The sterilizer **must** be able to sterilize packaged medical devices. A reusable medical device that is sterilized in sterilization packaging enables sterility to be maintained until point of use.
 - Verify the manufacturer's instructions for use (MIFU) of the sterilizer to confirm that it can sterilize packaged and lumened/cannulated devices.

Physicians should be wary of purchasing a sterilizer online or second-hand as the same requirements described above would apply. One example of a sterilizer that does not meet all three requirements described above is a sterilizer called the Prestige Classic 210006. Upon review, the Prestige Classic 210006 does have a valid Health Canada licence; however, based on its MIFU, this sterilizer is unable to sterilize packaged devices. Packaging materials represent a challenge for some smaller sterilizers as the steam from these sterilizers does not always penetrate sterilization packaging. The MIFU clearly states that the Prestige is "designed to sterilize solid (non-lumened) unwrapped instruments." This type of sterilizer may be used in settings such as tattoo facilities, however, it is not appropriate for medical settings such as physician clinical offices.

Physicians considering purchasing a tabletop steam sterilizer should review the College's [Checklist for Purchasing a Tabletop Steam Sterilizer](#) [3].

Are all disposable medical devices equal?

The POMDRA team is often asked where to purchase disposable/single-use medical devices, such as suture removal kits, for community-based clinics. Although there may be cost implications when purchasing supplies from a reputable medical supply company versus an online supplier, physicians must be confident that their products are approved for use in Canada and safe for use on patients. All disposable medical devices must be purchased from a company that has an active medical devices establishment licence (MDEL) from Health Canada. This confirms that the company is approved to sell medical devices in Canada.

Verify that a company has an active MDEL [here](#) [4].

For additional information on medical device reprocessing, visit the [POMDRA section](#) [5] on the College website.

References

1. Canadian Standards Association. User handbook for medical device reprocessing in community health care settings. Mississauga: Canadian Standards Association; 2014. 102 p. CSA Standard No.: SPE 1112-14.
2. British Columbia Ministry of Health. Best practice guidelines for cleaning, disinfection and sterilization of critical and semi-critical medical devices in BC health authorities [Internet]. Victoria: British Columbia Ministry of Health; 2007 [revision 2011 Dec; cited 2017 Oct 4]. 136 p. Available from: <http://www.health.gov.bc.ca/library/publications/year/2011/Best-practice-guidelines-cleaning.pdf> [6]

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[3]

<https://www.cpsbc.ca/files/pdf/POMDRA-Tabletop-Steam-Sterilizer-Checklist.pdf>

[4] <https://health-products.canada.ca/mdel-leim/index-eng.jsp>

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