WORLD TRADE ORGANIZATION

G/TBT/N/CAN/758

13 November 2025

(25-7507)

Committee on Technical Barriers to Trade

Original: English, French

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** CANADA **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Health Canada
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], Other:**
4.	**Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Medical equipment (ICS code(s): 11.040)
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Regulations Amending the Medical Devices Regulations (Establishment Licences) (30 pages, available in English and French) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://gazette.gc.ca/rp-pr/p1/2025/2025-11-08/html/reg1-fra.html
6.	**Description of content:** This proposal delivers on Phase II of Health Canada's commitments set out in the Departmental Forward Regulatory and Stock Review Plans to modernize the Medical Device Establishment Licensing (MDEL) framework, while enabling the oversight to better manage emerging health and safety risks. The proposed amendments would: • remove the requirement for importers with an MDEL to import from foreign distributors with an MDEL. • require all MDEL applicants to provide supplier information as part of their MDEL application and to update the supplier information once a year at annual licence review • Make explicit the requirement for manufacturers, importers and distributors to establish, implement and maintain all documented procedures relevant to their safety management activities. Most of the medical devices sold in Canada are imported, with a growing number of suppliers providing medical devices to the Canadian market. This, in addition to experimentation with regulatory flexibilities during the COVID-19 pandemic, demonstrates a need to update the current framework to allow Health Canada to continue to provide efficient, effective, and agile oversight of medical devices to protect the health and safety of people in Canada.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The objectives of this proposal are to modernize the MDEL framework to better

	respond to a rapidly innovative industry, while maintaining the oversight to better manage emerging health and safety risks. This includes: • Reducing unnecessary burden to facilitate international alignment; • Improving Health Canada's ability to identify and monitor non-compliant medical devices and establishments that may pose a risk of injury to health; and Providing certainty with respect to the requirements in the MDR.
8.	**Relevant documents:** Canada Gazette, Part I, 8 November 2025, pages 2186-2215 (available in English and French) https://gazette.gc.ca/rp-pr/p1/2025/2025-11-08/pdf/g1-15945.pdf
9.	**Proposed date of adoption:** On the day these regulations are registered **Proposed date of entry into force:** The proposed amendments to the MDR would come into force six months from the date of registration.
10.	**Provision of comments** **Final date for comments:** 17 January 2026 **[ ] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** Notification Authority and Enquiry Point Global Affairs Canada Technical Barriers and Regulations Division 111 Sussex Drive, Ottawa, Ontario K1A 0G2 ON K1A 0G Tel: +(343) 203-4273 Fax: +(613) 943-0346 E-mail: enquirypoint@international.gc.ca Site Web: http://www.international.gc.ca