NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** CANADA  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Health Canada  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  Canada's Notification Authority and Enquiry Point  Global Affairs Canada  Technical Barriers and Regulations Division  111 Sussex Drive  Ottawa (Ontario) K1A 0G2  Canada  Telephone: (343)203-4273  Fax: (613)943-0346  Email: [enquirypoint@international.gc.ca](mailto:enquirypoint@international.gc.ca) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****X],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical Devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** *Regulations Amending the Medical Devices Regulations (Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19)*,(56 pages, available in English and French) and the *Order Amending the Fees in Respect of Drugs and Medical Devices Order (COVID-19 Medical Devices),* (12pages, available in English and French). |
| **6.** | **Description of content:** Regulatory amendments to the *Medical Devices Regulations* (MDR) will create a new permanent regulatory framework for COVID-19 medical devices.  The amendments will allow for the continued importation and sale of over 800 COVID-19 medical devices authorized under *Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* (the third interim order).  As well, the amendments will maintain the regulatory flexibilities set out under the third interim order. The amendments will also permanently incorporate from the third interim order the expedited authorization pathways and certain flexibilities for COVID-19 medical devices that meet an urgent public health need.  Once a COVID-19 medical device is no longer considered an urgent public health need, manufacturers will need to comply with additional requirements (e.g., hold a Medical Device Establishment License, obtain a Quality Management System certificate that is in compliance with the Medical Device Single Audit Program, pay applicable fees) if they wish to continue to import or sell their medical device in Canada. These are requirements that are normally met by manufacturers for other medical devices authorized in Canada.  Consequential amendments will also be made to the MDR to provide greater alignment between the new regulatory framework and existing provisions.  The MDR regulatory package will be accompanied by the *Order Amending the Fees in Respect of Drugs and Medical Devices Order (COVID-19 Medical Devices)* (Fees Order)*.*  The Fees Order will be amended to include fees for Class II to IV COVID-19 medical devices once the devices no longer meet the definition of an urgent public health need*.* Fees will apply for:   * the examination of applications to amend an authorization being filed; and * annual right to sell fees   For COVID-19 medical devices that continue to meet an urgent public health need, fees will not apply. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the Regulations are to:   * enable manufacturers, importers and distributors to continue to import or sell COVID-19 medical devices authorized under the third interim order and provide a permanent regulatory framework for these devices; * maintain the regulatory flexibilities set out under the third interim order for COVID-19 authorizations while there is an urgent public health need for the devices; * enable new authorizations for COVID-19 medical devices and expanded use indications to be issued when there is an urgent public health need; * continue many of the regulatory obligations, and other requirements originally set out in the third interim order after the interim order expires, as well as existing applications in queue; and * introduce additional requirements for long-term oversight of the authorized devices that are in line with requirements other medical devices are subject to in the MDR, once a COVID-19 medical device is no longer considered required to meet an urgent public health need.   The objective of the Fees Order amendments is to introduce fees for Class II to IV COVID-19 medical devices once they no longer meet the definition of an urgent public health need. |
| **8.** | **Relevant documents:**  *Regulations Amending the Medical Devices Regulations (Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*   * *Canada Gazette*, Part II, 15 February 2023, pages 549 – 604   *Order Amending the Fees in Respect of Drugs and Medical Devices Order (COVID-19 Medical Devices)*   * *Canada Gazette*, Part II, 15 February 2023, pages 624 – 635   <https://www.gazette.gc.ca/rp-pr/p2/2023/2023-02-15/pdf/g2-15704.pdf> (available in English and French) |
| **9.** | **Proposed date of adoption:** On date of registration (3 February 2023)  **Proposed date of entry into force:** The MDR amendments and Fees Order amendments will come into force the day after Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 ceases to have effect (i.e., 22 February 2023). This will allow for the continued importation and sale of authorized COVID-19 medical devices. |
| **10.** | **Final date for comments:** Not Applicable; These regulatory amendments have been granted an exemption from publication in Canada Gazette, Part I, and therefore a pre-consultation was not conducted. |
| **11.** | **Texts available from: National enquiry point [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  The electronic version of the regulatory text can be found at:  Regulations Amending the Medical Devices Regulations (Interim Order No. 3 Respecting  the Importation and Sale of Medical Devices for Use in Relation to COVID-19  <https://canadagazette.gc.ca/rp-pr/p2/2023/2023-02-15/html/sor-dors19-eng.html> (English)  <https://canadagazette.gc.ca/rp-pr/p2/2023/2023-02-15/html/sor-dors19-fra.html> (French)  Order Amending the Fees in Respect of Drugs and Medical Devices Order (COVID-19 Medical Devices)  <https://canadagazette.gc.ca/rp-pr/p2/2023/2023-02-15/html/sor-dors21-eng.html> (English)  <https://canadagazette.gc.ca/rp-pr/p2/2023/2023-02-15/html/sor-dors21-fra.html> (French) |