NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

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| **1.** | **Notifying Member:** CHILE**If applicable, name of local government involved (Articles 3.2 and 7.2):** |
| **2.** | **Agency responsible:***Ministerio de Salud, MINSAL - Subsecretaría de Salud Pública* (Ministry of Health, Under-Secretariat for Public Health)**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:***Subsecretaría de Relaciones Económicas Internacionales,* SUBREI *- Ministerio de Relaciones Exteriores de Chile* (Under-Secretariat for International Economic Relations, Ministry of Foreign Affairs of Chile) |
| **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 or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical devices to detect Human Immunodeficiency Virus (HIV) |
| **5.** | **Title, number of pages and language(s) of the notified document:** *Decreto Exento N° 41 del Ministerio de Salud, de fecha 08 de junio de 2022: Incorpora al régimen de control sanitario establecido en el artículo 111 del Código Sanitario, a los dispositivos para detección de VIH que indica* (Ministry of Health Exempt Decree No. 41 of 8 June 2022 adding the indicated devices for HIV detection to the health control system established in Article 111 of the Health Code) (3 pages, in Spanish) |
| **6.** | **Description of content:** Ministry of Health Exempt Decree No. 41 of 2022 provides for the inclusion of the indicated devices for HIV detection in the health control system in Chile, which is governed by the provisions of Ministry of Health Supreme Decree No. 825 of 1998 approving the regulations on the control of products and goods for medical use. The health control involves various activities aimed at verifying that the devices meet certain technical specifications, which are listed in the notified Decree, in order to ensure their quality and guarantee that they function properly. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**Ministry of Health Supreme Decree No. 825 of 1998 approving the regulations on the control of products and goods for medical use:<https://www.bcn.cl/leychile/navegar?idNorma=141005>Health Code:<https://www.bcn.cl/leychile/navegar?i=5595&f=1968-01-31> |
| **9.** | **Proposed date of adoption:** 8 June 2022**Proposed date of entry into force:** 16 December 2022 |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:**Subsecretaría de Relaciones Económicas Internacionales - Ministerio de Relaciones Exteriores de ChileTeatinos 180, piso 11Tel.: (+56) 2 2827 5250Fax: (+56) 2 2380 9494Email: tbt\_Chile@subrei.gob.cl<https://www.minsal.cl/wp-content/uploads/2021/11/D-Ex-41-2022-Somete-a-control-ensayos-VIH-incluye-autotest-D-Of-16-06-2022.pdf>)<https://members.wto.org/crnattachments/2022/TBT/CHL/22_4168_00_s.pdf> |