NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** China  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** State Administration for Market Regulation (Standardization Administration of the P.R.C.)  **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:** |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical Devices; (HS: 902110); (ICS: 11.080.01) |
| **5.** | **Title, number of pages and language(s) of the notified document:** National Standard of the P.R.C., Sterilization of Health-Care Products — Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices (66 page(s), in Chinese) |
| **6.** | **Description of content:** This document specifies requirements for the development, validation and routine control of the ethylene oxide sterilization process for medical devices in both the industrial and health care facility settings, and it acknowledges the similarities and differences between the two applications.  This document applies to the ethylene oxide sterilization process during the production of medical devices. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Quality requirements |
| **8.** | **Relevant documents:**  - |
| **9.** | **Proposed date of adoption:** To be determined.  **Proposed date of entry into force:** To be determined. |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  WTO/TBT National Notification and Enquiry Center of the People's Republic of China Tel：+86 10 57954633/ 57954627 E\_mail: [tbt@customs.gov.cn](mailto:tbt@customs.gov.cn)  <https://members.wto.org/crnattachments/2021/TBT/CHN/21_7965_00_x.pdf> |