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 [****], 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):** Active implantable medical devices (HS code(s): 902150; 902190); (ICS code(s): 11.040.40) |
| **5.** | **Title, number of pages and language(s) of the notified document:** National Standard of the P.R.C., Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer; (42 page(s), in Chinese) |
| **6.** | **Description of content:** This document specifies the requirements that are generally applicable to active implantable medical devices.  This document applies not only to electrically powered active implantable medical devices, but also to active implantable medical devices powered by other energy sources(e.g., gas pressure or springs).  This document also applies to certain non-implantable parts and accessories of active implantable medical devices.  NOTE 1  For particular types of active implantable medical devices, these general requirements are supplemented or modified by the requirements of particular parts of the document.  The tests that are specified in this documents are type tests and are to be carried out on samples of an active implantable medical device to show compliance.  NOTE 2  The device that is commonly referred to as an active implantable medical device can be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Protection of the environment; Quality requirements |
| **8.** | **Relevant documents:**  - |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** 24 months after approval |
| **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/2023/TBT/CHN/23_8860_00_x.pdf> |