



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: CHINA If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: China Food and Drug Administration 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 [], 2.10.1 [], 5.6.2 [X], 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): Drugs HEALTH CARE TECHNOLOGY (ICS 11).
5. Title, number of pages and language(s) of the notified document: Rules for Unique Device Identification System for Medical Device (Draft) (5 page(s), in Chinese)
6. Description of content: The rules specify the content of the Unique Device Identification (UDI) system for medical device in China and the requirements of each chapter. It stipulates the responsibilities of the stakeholders, the application requirements of UDI system and the definitions of relevant terms.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: None
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 84603886/84603950 Fax: +86 10 84603811 E-mail: tbt@aqsiq.gov.cn