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):** Near infrared functional brain imaging device, near infrared spectral functional brain imaging system, quantitative brain function imaging device (HS code(s): 901820; 902750; 903149); (ICS code(s): 11.040.55) |
| **5.** | **Title, number of pages and language(s) of the notified document:** National Standard of the P.R.C., Medical electrical equipment –Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment; (32 page(s), in Chinese) |
| **6.** | **Description of content:** This document applies to the basic safety and essential performance of functional NIRS equipment intended to be used by themselves, or as a part of an ME system, for adjunctive diagnostic purposes.  Not included within the scope of this particular standard are:  a) the equipment, as a part of ME equipment, measures oxygen saturation of the haemoglobin in the micro vessels (capillaries, arterioles and venules);  b) near-infrared spectroscopy (NIRS) tissue oximeter equipment, which is not intended for obtaining functional NIRS equipment output;  c) pulse oximeter equipment, which is not intended for obtaining functional NIRS equipment output. The requirements for pulse oximeter equipment are found in YY 9706.261.  d) frequency-domain and time-domain equipment for functional near-infrared spectroscopy may be subject to different test procedures than those defined herein.  e) functional near-infrared spectroscopy equipment, which measure changes in the concentration of chromophores other than oxy- and deoxy-haemoglobin may be subject to different test procedures than those defined herein. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **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/2022/TBT/CHN/22_3481_00_x.pdf> |