



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: 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): High flow oxygen inhaler, High flow respiratory therapeutic instrument, Transnasal high flow oxygen therapeutic instrument, Respiratory humidification therapeutic instrument
5. Title, number of pages and language(s) of the notified document: National Standard of the P.R.C., Medical Electrical Equipment — Part 2-90:Particular Requirements for Basic Safety and Essential Performance of Respiratory High Flow Therapy Equipment; (66 page(s), in Chinese)
6. Description of content: This document specifies the basic safety and basic performance of high flow respiratory treatment equipment used in combination with accessories. Such medical devices are expected to be used for patients with spontaneous breathing; It is expected to be used in patients who need to improve alveolar gas exchange and who can benefit from receiving high flow humidified respiratory gas, including those whose upper respiratory tract is bypassed. High flow respiratory therapy equipment can be: Fully integrated ME equipment; Or an ME system formed by a discrete product portfolio. This document also applies to other types of respiratory devices with high flow respiratory treatment mode. The high flow respiratory therapy device is operable when moving. The provisions of this document also apply to accessories intended by the manufacturer for connection to high flow respiratory therapy equipment, and the characteristics of such accessories may affect the basic safety and basic performance of high flow respiratory therapy equipment.
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: 24 months after standard 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 https://members.wto.org/crnattachments/2022/TBT/CHN/22_2576_00_x.pdf