



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>CHINA</u> 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): Respiratory Gas Monitors Products (HS code(s): 901819); (ICS code(s): 11.040.10)
5. Title, number of pages and language(s) of the notified document: National Standard of the P.R.C., Medical Electrical Equipment-Part 2-55:Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors; (48 page(s), in Chinese)
6. Description of content: This document specifies particular requirements for the basic safety and essential performance of a respiratory gas monitor (RGM) and the requirements are listed as follows: <ul style="list-style-type: none">• anaesthetic gas monitoring,• carbon dioxide monitoring, and• oxygen monitoring. <p>NOTE 1: An RGM can be used as a stand-alone ME EQUIPMENT or integrated into other equipment, such as an anesthetic workstation or a ventilator.</p> <p>This document is not applicable to an RGM intended for use with flammable anesthetic agents.</p>
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 ChinaTel :

+86 10 57954633/ 57954627

E_mail: tbt@customs.gov.cn

https://members.wto.org/crnattachments/2022/TBT/CHN/22_2538_00_x.pdf