



### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>CHINA</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> State Administration for Market Regulation (Standardization Administration of the P.R.C.) <b>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:</b>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Photodynamic Therapy and Photodynamic Diagnosis Equipment
<b>5. Title, number of pages and language(s) of the notified document:</b> National Standard of the P.R.C., Medical Electrical Equipment-Part 2-75:Particular Requirements for the Basic Safety and Essential Performance of Photodynamic Therapy and Photodynamic Diagnosis Equipment; (23 page(s), in Chinese)
<b>6. Description of content:</b> This document applies to photodynamic therapy and photodynamic diagnosis equipment used to eliminate or alleviate disease, injury or disability.  This document does not apply to: <ul style="list-style-type: none"><li>• light therapy equipment intended for use in photothermal ablation, coagulation, and hyperthermia;</li><li>• low-level laser therapy equipment not intended for use with photosensitizer;</li><li>• illumination equipment intended for use in observation, monitoring, and diagnosis, not intended for use with photosensitizer.</li></ul>
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Consumer information, labelling; Protection of human health or safety; Quality requirements
<b>8. Relevant documents:</b> -
<b>9. Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b> 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](mailto:tbt@customs.gov.cn)

[https://members.wto.org/crnattachments/2022/TBT/CHN/22\\_2572\\_00\\_x.pdf](https://members.wto.org/crnattachments/2022/TBT/CHN/22_2572_00_x.pdf)