



12 May 2026

(26-3548)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<p>1. Notifying Member: <u>THAILAND</u> If applicable, name of local government involved (Articles 3.2 and 7.2):</p>
<p>2. Agency responsible: Food and Drug Administration (Thai FDA) Medical Device Control Division 88/24 Tiwanon Road, Nonthaburi 11000, Thailand Tel: (662)590 7283 Email: mdregulation@fda.moph.go.th</p>
<p>3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], Other:</p>
<p>4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Medical Devices</p>
<p>5. Details of notified document(s) (title, number of pages and languages, means of access): Draft Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With B.E.; (9 page(s), in Thai) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2026/TBT/THA/26_02495_00_x.pdf WTO/TBT Enquiry Point and Notification Authority Thai Industrial Standards Institute (TISI), Ministry of Industry Tel: (662)430 6831 ext. 2130 Fax: (662)354 3041 E-mail: thaitbt@tisi.mail.go.th Website: https://www.tisi.go.th</p>
<p>6. Description of content: The Minister of Public Health hereby issues the draft Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With B.E. This draft Notification repeals the following Notifications:</p> <ol style="list-style-type: none">1. Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With B.E. 2563 (2020) (Repealed)2. Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With (No.2) B.E. 2563 (2020) (Repealed)3. Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With (No.3) B.E. 2563 (2020) (Repealed)4. Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With (No.4) B.E. 2567 (2024) (Repealed)

<p>This draft Notification prescribes requirements for manufacturers, importers, and distributors and provides a transition period for manufacturers and importers prior to the entry into force of this Notification.</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety</p>
<p>8. Relevant documents:</p> <ul style="list-style-type: none"> • Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With B.E. 2563 (2020) (Repealed) • Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With (No.2) B.E. 2563 (2020) (Repealed) • Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With (No.3) B.E. 2563 (2020) (Repealed) • Notification of the Ministry of Public Health Re: Medical Device Standards that Manufacturers or Importers Must Comply With (No.4) B.E. 2567 (2024) (Repealed)
<p>9. Proposed date of adoption: To be determined</p> <p>Proposed date of entry into force: From the day following the date of publication in the Government Gazette</p>
<p>10. Provision of comments</p> <p>Final date for comments: 11 July 2026</p> <p>[X] 60 days from notification</p> <p>Contact details of agency or authority designated to handle comments regarding the notification:</p> <p>WTO/TBT Enquiry Point and Notification Authority Thai Industrial Standards Institute (TISI), Ministry of Industry Tel: (662)430 6831 ext. 2130 Fax: (662)354 3041 E-mail: thaitbt@tisi.mail.go.th Website: https://www.tisi.go.th</p>