



### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>THAILAND</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Food and Drug Administration (Thai FDA) Medical Device Control Division 88/24 Tiwanon Road, Nonthaburi 11000, Thailand Tel: (662)590 7283 Email: <a href="mailto:mdregulation@fda.moph.go.th">mdregulation@fda.moph.go.th</a>
<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 codes or national tariff lines. ICS numbers may be provided in addition, where applicable):</b> Medical Devices
<b>5. Details of notified document(s) (title, number of pages and languages, means of access):</b> Draft Notification of the Ministry of Public Health Re: Rules, Procedures and Conditions for the Use of Medical Devices in Clinical Investigations B.E. ...; (7 page(s), in Thai) <b>Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:</b> <a href="https://members.wto.org/crnattachments/2026/TBT/THA/26_02489_00_x.pdf">https://members.wto.org/crnattachments/2026/TBT/THA/26_02489_00_x.pdf</a> 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: <a href="mailto:thaitbt@tisi.mail.go.th">thaitbt@tisi.mail.go.th</a> Website: <a href="https://www.tisi.go.th">https://www.tisi.go.th</a>
<b>6. Description of content:</b> The Minister of Public Health hereby issues the draft Notification of the Ministry of Public Health Re: Rules, Procedures and Conditions for the Use of Medical Devices in Clinical Investigations B.E. .... This draft Notification repeals the Notification of the Ministry of Public Health Re: Rules, Procedures and Conditions for the Use of Medical Devices in Clinical Investigations B.E. 2566 (2023). This draft Notification shall apply to the following: <ol style="list-style-type: none"><li>1. Class 4 medical devices</li><li>2. All implantable medical devices and long-term surgically invasive medical devices</li><li>3. Novel medical devices not previously registered in any country</li><li>4. Medical devices defined by the Secretary-General of the Food and Drug Administration</li></ol>

<p>5. Class 2 and Class 3 medical devices with novel indications not previously registered in any country</p> <p>This draft Notification provides definitions of terms including 'clinical investigation', 'analytical performance study', 'investigational medical device', 'clinical investigation plan', 'sponsor', 'investigator', 'serious adverse event', and 'adverse device effect'. In addition, it prescribes requirements for manufacturers, importers, investigators and sponsors, as well as a transition period for persons who have manufactured or imported medical devices for clinical investigation and for those currently conducting clinical investigations.</p>
<p><b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> for the efficiency of clinical investigations and the safety of clinical investigation subjects</p>
<p><b>8. Relevant documents:</b></p> <p>Notification of the Ministry of Public Health Re: Rules, Procedures and Conditions for the Use of Medical Devices in Clinical Investigations B.E. 2566 (2023) (Repealed)</p>
<p><b>9. Proposed date of adoption:</b> To be determined</p> <p><b>Proposed date of entry into force:</b> 30 days after the date of publication in the Government Gazette</p>
<p><b>10. Provision of comments</b></p> <p><b>Final date for comments:</b> 10 July 2026</p> <p><b>[X] 60 days from notification</b></p> <p><b>Contact details of agency or authority designated to handle comments regarding the notification:</b></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: <a href="mailto:thaitbt@tisi.mail.go.th">thaitbt@tisi.mail.go.th</a>          Website: <a href="https://www.tisi.go.th">https://www.tisi.go.th</a></p>