



18 October 2021

(21-7859)

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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

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> European Commission <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> European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a> Website: <a href="http://ec.europa.eu/growth/tools-databases/tbt/en/">http://ec.europa.eu/growth/tools-databases/tbt/en/</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 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> In vitro diagnostic medical devices; Medical equipment (ICS 11.040), In vitro diagnostic test systems (ICS 11.100.10)
<b>5. Title, number of pages and language(s) of the notified document:</b> Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices (13 page(s), in English)
<b>6. Description of content:</b> Regulation (EU) 2017/746 on in vitro diagnostics medical devices (IVD Regulation) will apply from 26 May 2022. It establishes a new regulatory framework for <i>in vitro</i> diagnostic medical devices including conformity assessment procedures. It was notified to the WTO as notification <a href="#">G/TBT/N/EU/72</a> .  Due to the additional resources required to address the COVID-19 pandemic, it is now clear that national authorities, health institutions, notified bodies and economic operators will not be in a position to ensure the proper implementation and application of the Regulation from the date of application.  With only six notified bodies designated so far, there is a grave shortage of notified body capacity, making it impossible for manufacturers to conduct the legally required conformity assessment procedures in time. In addition, due to COVID-19 travel restrictions, notified bodies were not able to carry out the required on-site audits at the manufacturers' premises to verify the manufacturing and other relevant processes. This risks significant disruption in the supply of a multitude of <i>in vitro</i> diagnostic medical devices (e.g. HIV tests, pregnancy tests or SARS-CoV-2 tests) on the European Union market.  The draft measure proposes a staggered set of transition periods for devices that are required to undergo conformity assessment procedures involving a notified body. The

	length of the transition periods depends on the risk class of the devices, with shorter transition periods for higher risk devices and longer periods for lower risk ones. In addition, the notified draft proposes a deferred application of the requirements for 'in-house devices', i.e. those made and used within the same health institution.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> The draft measure maintains the objectives of Regulation (EU) 2017/746 to ensure a high level of safety and performance of devices by enhancing their oversight by notified bodies and, in the case of in-house devices, by setting uniform requirements on health institutions. It only provides for the necessary additional time to achieve this objective whilst ensuring the protection of human health and safety, in particular to prevent shortage of essential IVD devices. Having regard to the usual length of conformity assessment procedures, the amendment to Regulation 2017/746 needs to be adopted as quickly as possible in order to ensure legal certainty for all actors, including manufacturers and notified bodies, ahead of the date on which the Regulation (EU) 2017/746 will become applicable. Therefore, given that this notified draft only amends the previously notified measure (Regulation (EU) 2017/746) by extending its transitional provisions' scope and timelines, a reduced commenting period is justified.; Other
8.	<b>Relevant documents:</b>  Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on <i>in vitro</i> diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p. 176).  <a href="#">EUR-Lex - 02017R0746-20170505 - EN - EUR-Lex (europa.eu)</a>
9.	<b>Proposed date of adoption:</b> October/November 2021 (as early as possible)  <b>Proposed date of entry into force:</b> On the day of its publication in the Official Journal of the European Union
10.	<b>Final date for comments:</b> 10 days from notification
11.	<b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b>  European Commission EU-TBT Enquiry Point Fax: + (32) 2 299 80 43 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a>  The text is available on the EU-TBT Website: <a href="http://ec.europa.eu/growth/tools-databases/tbt/en/">http://ec.europa.eu/growth/tools-databases/tbt/en/</a>  <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2021%3A627%3AFIN&amp;qid=1634295896548">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2021%3A627%3AFIN&amp;qid=1634295896548</a> <a href="https://members.wto.org/crnattachments/2021/TBT/EEC/21_6588_00_e.pdf">https://members.wto.org/crnattachments/2021/TBT/EEC/21_6588_00_e.pdf</a>