



2 September 2024

(24-6097)

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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 [X], 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> <i>In vitro</i> diagnostic medical devices
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Commission Implementing Regulation amending Implementing Regulation (EU) 2022/1107 laying down common specifications for certain class D <i>in vitro</i> diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council; (4 page(s), in English), (41 page(s), in English)
<b>6. Description of content:</b> This draft Commission Implementing Regulation adds common specifications for some high-risk <i>in vitro</i> diagnostic medical devices in accordance with Art. 9 of Regulation (EU) 2017/746, notably in relation to their performance evaluation. It also makes a number of editorial corrections to existing specifications.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, Article 9 of Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices gives the Commission the possibility to adopt common specifications in respect of certain requirements of the said Regulation.  Based on that legal basis, Commission Implementing Regulation (EU) 2022/1107 sets out common specifications for 16 types of high-risk (class D) devices with regard to general safety and performance requirements, performance evaluation, post-market performance follow-up and performance studies.

The present implementing act amends Commission Implementing Regulation (EU) 2022/1107 to add common specifications for other types of class D devices, namely those detecting the following pathogens: hepatitis E virus, *Toxoplasma gondii*, *Plasmodium* (malaria) and four types of arboviruses – dengue, Chikungunya, West Nile and Zika viruses. These devices are considered as high risk and classified in class D when they are intended by the manufacturer to be used in transfusion of blood, transplantation of tissues or organs, or for cell administration. These specifications are not covered by existing harmonised standards and are also needed to address public health concerns about safety of blood, tissues, organs or cells for potential recipients. Some corrections are also made to the existing specifications based on the experience with their use or to reflect the state of the art.

The common specifications provide a presumption of conformity with the corresponding legal requirements of Regulation (EU) 2017/746. Therefore they will greatly facilitate the work of the manufacturer in complying with the legislation, the assessment by the notified bodies, testing by EU reference laboratories and oversight by the national competent authorities. Moreover, they will facilitate a harmonised approach to conformity assessment of these devices across the Union and the achievement of consistently high standards of device performance; Protection of human health or safety; Harmonization

**8. Relevant documents:**

Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council, OJ L 178, 5.7.2022, p. 3:

[EUR-Lex - 32022R1107 - EN - EUR-Lex \(europa.eu\)](#)

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176:

[EUR-Lex - 32017R0746 - EN - EUR-Lex \(europa.eu\)](#)

**9. Proposed date of adoption:** 4th Quarter 2024

**Proposed date of entry into force:** 20 days from publication in the Official Journal of the EU. There is a transition period of 2 years following entry into force of the regulation.

**10. Final date for comments:** 60 days from notification

**11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

European Commission,  
EU-TBT Enquiry Point,  
Fax: + (32) 2 299 80 43,

E-mail: [grow-eu-tbt@ec.europa.eu](mailto:grow-eu-tbt@ec.europa.eu)

The text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/>

[https://members.wto.org/crnattachments/2024/TBT/EEC/24\\_05775\\_00\\_e.pdf](https://members.wto.org/crnattachments/2024/TBT/EEC/24_05775_00_e.pdf)

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