Message 001

Communication from the Commission - TRIS/(2025) 0218

Directive (EU) 2015/1535

Notification: 2025/0043/ES

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta’ dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20250218.EN

1. MSG 001 IND 2025 0043 ES EN 24-01-2025 ES NOTIF

2. Spain

3A. Ministerio de Asuntos Exteriores, Unión Europea y Cooperación
Dirección General de Coordinación del Mercado Interior y Otras Políticas Comunitarias
Subdirección General de Asuntos Industriales, Energéticos, de Transportes y Comunicaciones y de Medio Ambiente
Plaza del Marqués de Salamanca, 8 – 28006 Madrid
Correo electrónico: d83_189@ue.mae.es

3B. Ministerio de Sanidad.
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
DEPARTAMENTO DE PRODUCTOS SANITARIOS
C/CAMPEZO 1 28022 MADRID
TLF: 918225261
FAX:918225289
Correo electronico: cruizv@aemps.es

4. 2025/0043/ES - S10S - Medical devices

5. Draft Royal Decree on the regulation of in vitro diagnostic medical devices.

6. In vitro diagnostic medical devices.

7.

8. The direct application of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, as of 26 May 2022, requires the adaptation of the current national legislation on in vitro diagnostic medical devices, in order to repeal those areas relating to matters that will be directly regulated by the provisions of the Regulation and, at the same time, to develop the necessary regulatory measures for aspects where, in accordance with that Regulation, Member States are required to establish regulations at a national level.

This standard is necessary to regulate, at national level, in vitro diagnostic medical devices for human use and their accessories, and in particular:

a) The competent authority and health guarantees.
b) The procedures for granting prior licences for the operation of facilities.
c) Genetic tests considered as in vitro diagnostic medical devices for human use, included in the definition set out in Article 2(2) of 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.
d) Reference laboratories.
e) The requirements and actions of notified bodies.
f) The making available on the market and putting into service in Spain.
g) Trade on the European Union market and on the foreign market.
h) Performance studies.
i) The vigilance system.
j) Market inspection and surveillance, and health protection measures.

9. The regulation has the following specific objectives for in vitro diagnostic medical devices:

- Repeal, in general, Royal Decree 1662/2000 of 29 September 2000 on in vitro diagnostic medical devices – with the exception of Articles 9, 10, 11, 12, 18 (paragraphs 5 and 6), 20, 25, 26 and 27 – in view of the direct application of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, as of 26 May 2022.
- Develop the necessary regulatory measures for those areas where the Regulation has determined that it will be the Member States that will lay down the rules at national level.
- Adapt, adopt or maintain the measures required by national legislation.

10. References to basic texts:

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

****

European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu