Message 001

Communication from the Commission - TRIS/(2025) 3762

Directive (EU) 2015/1535

Notification: 2025/0787/PT

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: 20253762.EN

1. MSG 001 IND 2025 0787 PT EN 23-12-2025 PT NOTIF

2. Portugal

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4. 2025/0787/PT - S10S - Medical devices

5. Approves the list of single-use medical devices whose reprocessing is prohibited

6. Single-use medical devices whose reprocessing is prohibited for reasons of patient safety, clinical risk and technical limitations, in accordance with Regulation (EU) 2017/745.

7.

8. This order approves the list of single-use medical devices whose reprocessing is prohibited in national territory, in accordance with Article 17 of Regulation (EU) 2017/745 and Implementing Regulation (EU) 2020/1207.

The list identifies categories of devices which, because of their technical, clinical or safety characteristics, are not suitable for reprocessing.

The measure aims to ensure a high level of protection of public health and patient safety while ensuring a harmonised application of Union law in the field of medical devices.

9. The adoption of this Ordinance is justified by the need to exclude from reprocessing single-use medical devices presenting specific risks or technical limitations incompatible with safe re-use.

The measure stems directly from the European regulatory framework applicable to medical devices and aims to ensure the protection of public health, clinical safety and confidence in the healthcare system, without introducing discrimination or disproportionate barriers to the internal market.

10. References of the Basic Texts: 2021/0130/P

The basic texts were forwarded with an earlier notification:
2021/0130/P

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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