Message 001

Communication from the Commission - TRIS/(2025) 2648

Directive (EU) 2015/1535

Notification: 2025/0544/FR

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: 20252648.EN

1. MSG 001 IND 2025 0544 FR EN 26-09-2025 FR NOTIF

2. France

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4. 2025/0544/FR - S00S - HEALTH, MEDICAL EQUIPMENT

5. Order on reconditioning pursuant to Article L5212-1-1 of the Public Health Code

6. Medical devices for individual use (pursuant to Article L5212-1-1 of the Public Health Code)

7.

8. Pursuant to Article L5212-1-1 of the Public Health Code, this Order lays down the conditions to which reconditioning operations are subject in order to ensure the quality and safety of use of the reconditioned device. These conditions are established by a mandatory technical standard.
Decree No 2025-247 of 17 March 2025 on the reconditioning of certain medical devices defines the rules guaranteeing the quality and safety of reconditioned medical devices after they have been put into service, as well as the rules governing coverage by the French national health insurance scheme (national social security system) and the traceability requirements for these products. This Decree was notified under the 2015/1535 procedure (2023/0135/F) on 24 March 2023.
As a reminder, Regulation (EU) 2017/745 of 5 April 2017 on medical devices does not harmonise rules relating to the further making available on the market of medical devices after they have already been put into service such as in the context of second-hand sales, as stated in recital 3.

9. The measure pursues a twofold general purpose for the product categories identified in the Order in question:

- to avoid waste and premature obsolescence by extending the period of use of the medical devices concerned, while ensuring their safe use by creating a technical standard for reconditioning, issued for a period of 4 years by a certifying body accredited by the French Accreditation Committee or by another national accreditation body referred to in Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, setting out the requirements for accreditation for reconditioning and with the traceability of those devices in an information system called Registration relating to the official movement of medical devices (ECO-DM) provided for in Article L165-1-8 of the Social Security Code;
- to allow the patients concerned greater access to these reconditioned devices – under all the required health safety conditions – and to be reimbursed by health insurance with limited personal expenses.

10. References to basic texts: 2023/0135/F

The basic texts were forwarded with an earlier notification:
2023/0135/F

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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