

Message 001

Communication from the Commission - TRIS/(2025) 2361

Directive (EU) 2015/1535

Notification: 2025/0487/FR

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – 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 - Nezahtuje 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 késésekét - Non fa decorrere la mora - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ 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: 20252361.EN

1. MSG 001 IND 2025 0487 FR EN 02-09-2025 FR NOTIF

2. France

3A. Ministères économiques et financiers

Direction générale des entreprises

SCIDE/SQUALPI - Pôle Normalisation et réglementation des produits

Bât. Sieyès -Teledoc 143

61, Bd Vincent Auriol

75703 PARIS Cedex 13

3B. Ministère de la santé et de l'accès aux soins

Direction de la sécurité sociale

Sous-direction du financement du système de soins

Bureau des produits de santé - 1C

14, avenue Duquesne

75350 PARIS 07 SP

4. 2025/0487/FR - S00S - HEALTH, MEDICAL EQUIPMENT

5. Order establishing the list of medical devices for individual use that may be reconditioned pursuant to Article L. 5212-1-1 of the French Public Health Code

6. Medical devices for individual use (pursuant to Article L.5212-1-1 of the Public Health Code)

7.

8. Pursuant to Article L.5212-1-1 of the French Public Health Code, this order sets out the list of devices for individual use that may be reconditioned. Fifteen categories of medical devices were selected after consultation.

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 the provisions governing the making available on the market of medical devices after they have already been put into service, in particular 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:

- 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 four 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 restoration in good working order 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 L. 165-1-8 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

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu