



Notification Number: 2006/451/F

Order on the sterilisation of medical devices outside of healthcare establishments.

Date received : 18/08/2006
End of Standstill : 20/11/2006 (19/02/2007)
Issue of comments by : Commission, Czech Republic
Issue of detailed opinion by : Commission

Message

Message 002

Communication from the Commission - SG(2006) D/52013
Directive 98/34/EC
Translation of the message 001
Notification: 2006/0451/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata -
Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora -
Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien
- Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud -
Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200602013.EN)

1. Structured Information Line

MSG 002 IND 2006 0451 F EN 20-11-2006 18-08-2006 F NOTIF 20-11-2006

2. Member State

France

3. Department Responsible

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3. Originating Department

Ministère de la santé et des solidarités. Direction générale de la santé. Service prévention, programmes de santé et gestion des risques. Bureau SD5C.



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4. Notification Number

2006/0451/F - S10S

5. Title

Order on the sterilisation of medical devices outside of healthcare establishments.

6. Products Concerned

All sterilisation apparatus using dry heat shall be prohibited for the sterilisation of medical devices. Only steam sterilisers shall be authorised.

7. Notification Under Another Act

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8. Main Content

Within the context of combating infections linked to healthcare, the sterilisation of reusable medical devices by means of dry heat shall be prohibited for all healthcare professionals operating outside of healthcare establishments. Only steam sterilisation shall be authorised.

Keywords: dry-heat sterilisation, steam sterilisation, medical devices, healthcare professionals.

9. Brief Statement of Grounds

Dry-heat sterilisation is already forbidden in healthcare establishments as a result of random efficiency, the risk of alteration of medical devices through excessively high temperatures and the fixing of proteins, in particular non-conventional transmissible agents (NCTAs such as prions).

This prohibition is being extended to healthcare professionals operating outside of healthcare establishments.

10. Reference Documents - Basic Texts

Article L. 3114-6 of the Public Health Code: 'The healthcare professionals and directors of biomedical analysis laboratories referred to in Book II of Part 6 of the present code, operating outside of healthcare establishments, shall ensure the prevention of any infections relating to their prevention, diagnostic and care activities. Where necessary, the rules to which they must conform shall be laid down by means of orders. »

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

a) NO



14. Fiscal measures

b) NO

15. Impact assessment

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16. TBT and SPS aspects

TBT aspect (Agreement on Technical Barriers to Trade)

a) NO

b)

iii) The draft does not have a significant effect on international trade.

SPS aspect (Agreement on Sanitary and Phytosanitary Measures)

a) NO

b)

i) The draft is not a sanitary or phytosanitary measure pursuant to Annex A to the SPS Agreement.

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