Notification Number: 2000/611/F

SOOS - Draft Order establishing the list of categories for medical devices mentioned in point 5 of Article L. 5211-6 of the Public Health Code

Date received	:	12/10/2000
End of Standstill	:	Closed
Issue of comments by	:	Denmark,Italy
Issue of detailed opinion by	:	Ireland

Message

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Représentation Permanente de l'Irlande
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Représentation Permanente du Royaume-Uni
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Message 002

Communication from the Commission - SG(2000) D/52242
Directive 98/34/EC
Translation of the message 001
Notification: 2000/611/F

(MSG: 200002242.EN)

1. Structured Information Line
MSG 002 IND 2000 0611 F EN 12-10-2000 F NOTIF

2. Member State
FRANCE

3. Department Responsible
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4. Notification Number
2000/611/F

5. Title
SOOS - Draft Order establishing the list of categories for medical devices mentioned in point 5 of Article L. 5211-6 of the Public Health Code

6. Products Concerned
Medical devices.

7. Notification Under Another Act
No.

8. Main Content
Article L. 5211-4 of the Public Health Code stipulates that after certification of conformity with the essential requirements concerning the health and safety of patients, users and third parties, medical devices whose design or manufacture could be at the origin of specific health risks may only be put into service, made available free of charge or in return for payment, or used if they have been declared at least three months prior to their placing on the market to AFSSAPS (French Agency for safety of health products).

A draft Decree, which has also been the subject of a notification, lays down the typology of the categories of medical devices subject to this declaration as well as the attached procedure. It also specifies that the list of these categories is laid down by an Order from the Minister responsible for health.

The text which is notified to you constitutes the draft of the first Order laying down this list, on the understanding that this Order must be re-examined at least every two years (provision provided for by the Decree).

9. Brief Statement of Grounds
See explanatory statement set out for the draft Decree

10. Reference Documents - Basic Texts
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Public Health Code, particularly Articles L. 5211-4 and L. 5211-6 (Point 5)

Draft Decree concerning medical devices which must be declared prior to their placing on the market and amending Title V(a) of the Public Health Code

11. Invocation of the Emergency Procedure
Yes

12. Grounds for the Emergency
It is necessary to swiftly adopt this Decree and this Order for the protection of public health. According to information from AFSSAPS, the measures likely to be taken pursuant to these texts could, for example, affect the potential risk of transmission of the BSE agent to man (see explanatory statement supplementing the notification sheet).

13. Confidentiality
No

14. Fiscal measures
No

David O'Sullivan

General Secretary
European Commission