Notification Number: 2009/708/F

Draft Decree on the resale of second-hand medical devices, laid down in implementation of Article L. 5212-1 and amending the Public Health Code

Date received : 30/12/2009

End of Standstill : 31/03/2010

Message

Message 002

Communication from the Commission - SG(2010) D/50024
Directive 98/34/EC
Translation of the message 001
Notification: 2009/0708/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 késéseket - Ma' jiftaħx 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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201000024.EN)

1. Structured Information Line
MSG 002 IND 2009 0708 F EN 31-03-2010 30-12-2009 F NOTIF 31-03-2010

2. Member State
F

3. Department Responsible
Délégué interministériel aux normes – SQUALPI – Bâtiment Le Bervil - 12, rue Villiot – 75572 PARIS Cedex 12
d9834.france@finances.gouv.fr
tél : 01 53 44 98 24 – fax : 01 53 44 98 88

3. Originating Department
Ministère de la Santé et des Sports,
DGS/PP3
14 avenue Duquesne, 75350 PARIS 07 SP

4. Notification Number
2009/0708/F - S10S Medical devices

5. Title
Draft Decree on the resale of second-hand medical devices, laid down in implementation of Article L. 5212-1 and amending the Public Health Code

6. Products Concerned
Medical devices

7. Notification Under Another Act
This notification is issued in accordance with article 8 of amended Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

8. Main Content
This draft Decree, the first version of which was notified to the European Commission on 11 October 2006 (Notification 2006/0550/F), lays down the terms and conditions for application of Article L. 5212-1 of the Public Health Code, which covers the resale of certain second-hand medical devices by inserting a new section entitled “resale of second-hand medical devices” consisting of eight articles (R. 5212-35-1 to R. 5212-35-7 and R. 5461-1) in the chapter relating to medical devices vigilance.

The current wording of this draft Decree lays down provisions that aim to ensure the recognition of certificates issued ad hoc by bodies in other Member States (article R. 5212-35-2) and clarify the field of application with regards to second-hand medical devices from third countries (article R. 5212-35-3) in accordance with the requests made in the detailed opinion of 4 January 2007 of the European Commission.

Furthermore, Article L. 5212-1 of the Public Health Code is being amended at regulatory level and the provisions concerning authorised bodies have been deleted to transpose Directive 2006/123/EC on services in the internal market.

Apart from these amendments, all other provisions of this draft Decree shall remain unchanged. Article R. 5212-35-1 sets out the field of application for the provisions relating to the resale of second-hand medical devices. Article R. 5212-35-3 defines a second-hand medical device as a medical device “as is” compared to a medical device that is new or reconditioned. Article R. 5212-35-4 lays down the conditions for the issue of the technical certificate. Articles R. 5212-35-5 and R. 5212-35-6 provide a list of documents that must be provided by the reseller to the buyer, depending on the certificate issued. In accordance with article R. 5212-35-7, the reseller shall pass on the technical certificate to the buyer on purchase. A fine has been added to article R. 5461-1 of the Public Health Code for any failure to meet the obligation set out in Article L. 5212-1 and the provisions of this draft.

9. Brief Statement of Grounds
The provisions of the Public Health Code, resulting from the transposition of Directive 90/385/EEC of 20 June 1990 and Directive 93/42/EEC of 14 June 1993, provide a framework for the placing on the market of medical devices, taken to mean the supply, either in return for payment or free of charge, of new or reconditioned

devices (Article R. 5211-4), by subjecting such supplies to certification procedures for the compliance of devices with the essential health and safety requirements laid down by the Directive and to the prior obtaining of a CE marking. By contrast, there was no framework provided for the resale of second-hand medical devices at national or at Community level. It thus appeared necessary, for reasons of health and safety, to impose on operators of highly sensitive medical devices who engage in the resale of such devices an obligation to supply proof that these devices operate correctly, in accordance with the specifications of the manufacturer, and have been maintained correctly.

10. Reference Documents - Basic Texts
a) Public Health Code (Articles L.5212-1, R. 5211-4, R. 5212-26 to R. 5212-35 and R. 5461-1)
b) Penal Code (Article R. 610-1)

11. Invocation of the Emergency Procedure
NO

12. Grounds for the Emergency
/

13. Confidentiality
NO

14. Fiscal measures
NO

15. Impact assessment
/

16. TBT and SPS aspects
a) NO
b)
iii) The project has no significant impact on international trade

a) NO
b)
iii) The project has no significant impact on international trade.

Catherine Day
Secrétaire général
Commission européenne

Point de contact Directive 98/34
Fax: (32-2) 296 76 60
email: dir83-189-central@ec.europa.eu

---
sent to :

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Frau MARKL Iris

Työ- ja elinkeinoministeriö
Ms. Leila Vilhunen

Malta standards Authority
Sarah Jane Meli

Kommerskollegium
Ms Gunnel Fälth

Office of standards, metrology & Testing Kralikova Dana
.

BundesMinisterium für Wirtschaft und Technologie (Referat EB2)
Frau Kathrin Lettgen

Représentation Permanente de la France
.

Ministerio dell'industria
Sr. CASTIGLIONI Enrico

Ministry of Economy Dept for Economic Regulations
Mrs Barbara H. Kozlowska

Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Frau Brigitte WIKGOLM

Représentation Permanente de la Belgique auprès de l'Union européenne
.

Ministerio de Asuntos Exteriores y Coop. DG de Coordinación del Mercado Interior
Juan Carlos Calvo Huerta

Min. of Economic Affairs & Communication
Mr. Karl Stern

Délégation Interministérielle aux Normes
Mme PORTOU-DUPIN

Min. of Industry, Energy & Technology
Mr K. Polychronidis

CU N Lovseth Hanne Leen
.

Ministerie van Financiën Belastingsdienst - Douane Noord / CDIU
De Heer IJ.G. van der Heide

Instituto Portugês da Qualidade
Sra Engª. Anete Freitas

Bundesministerium für Wirtschaft undBund Arbeit - Abteilung C2/1
Franz BORTH

Institut Belge de Normalisation
Mme F. Hombert

European Free Trade Association
Mr. Robert Murphy

EU internal market coordination (Ministry of Economics)
Mr. Dainis Matulis

BELNotif (Qualité et Sécurité) SPF Economie,PME,Classes moyennes, Energ
M. Paul Caruso

Cyprus org. for the promotion of quality Ministry of Commerce, Industry & Tourism
M. Antonis Ioannou

AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARI Comisión Interministerial para la Ordena
Mª Luisa Aguilar Zambalamberri

ELOT
Mrs. Tzolou Afroditi

NSAI
Mr Tony Losty

Lithuanian Standards Board
Daiva Lesickiene

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT

Czech Office for Standards, Metrology and testing
Mrs Lucie Ruzickova

Erhvervs- og Byggestyrelsen/Danish Enterprise & Construction Authority
Bjarne Bang Christensen

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

Ministero dello sviluppo economico Dip.to Impresa e Internazionalizzazione
Sr. CASTIGLIONI Enrico

Slovenian Institute for Standardization SIST
Mrs Jozica Skof Nikolic

Department for Business, Innov. & Skills
Mr Philip Plumb

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Ida CSISZAR

SPF Economie Direction générale Qualité et Sécurit
Paul Caruso

State Agency for Metrological and Technical Surveillance
Violetta Veleva

SL
.

CU FL-Amt für Handel und Transport (TPMN)
Dipl. Ing. FH Thomas Näf

Hungarian Notification Centre Ministry of National Development and Eco
Mr Zsolt Fazekas

Institut luxembourgeois de la normalisat (ILNAS)
Mr Manuel Turmes

Service de l' Energie de l' Etat
M. Miguel Borges

Représentation Permanente du Luxembourg
.

Office of standards, metrology & Testing Director of the department of European I
Mrs Kvetoslava STEINLOVA

---

sent to :

Työ- ja elinkeinoministeriö
Ms. Leila Vilhunen

Malta standards Authority
Sarah Jane Meli

Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

CU N Lovseth Hanne Leen
.

European Free Trade Association
Mr. Robert Murphy

AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARI Comisión Interministerial para la Ordena
Mª Luisa Aguilar Zambalamberri

NSAI
Mr Tony Losty

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

Représentation Permanente du Royaume-Uni
.

Department for Business, Innov. & Skills
Mr Philip Plumb

State Agency for Metrological and Technical Surveillance
Violetta Veleva

SL
.

Hungarian Notification Centre Ministry of National Development and Eco
Mr Zsolt Fazekas

Représentation Permanente de l'Irlande
Denis Colfer