Notification Number: 2010/813/F

Draft decree on the resale of second-hand in vitro diagnostic medical devices, passed in implementation of Article L. 5222-2 of the Code de la santé publique

Date received : 27/12/2010

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Message

Message 002

Communication from the Commission - SG(2010) D/53218
Directive 98/34/EC
Translation of the message 001
Notification: 2010/0813/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: 201003218.EN)

1. Structured Information Line
MSG 002 IND 2010 0813 F EN 27-12-2010 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
Ministère du Travail, de l'Emploi et de la Santé,
DGS/PP3

14 avenue Duquesne, 75350 PARIS 07 SP

4. Notification Number
2010/0813/F - S10S

5. Title
Draft decree on the resale of second-hand in vitro diagnostic medical devices, passed in implementation of Article L. 5222-2 of the Code de la santé publique

6. Products Concerned
In vitro diagnostic medical devices

7. Notification Under Another Act
-

8. Main Content
The purpose of this draft decree is to lay down the arrangements for the application of Article L. 5222-2 of the Code de la santé publique, in particular the arrangements for the drawing-up of technical certificates prior to the resale of second-hand in vitro diagnostic medical devices, by inserting within the chapter dealing with medical device vigilance a new section entitled “resale of second-hand in vitro diagnostic medical devices” comprising six articles (R. 5222-20 to R. 5222-25).
Article L. 5222-2 of the Code de la santé publique, in implementation of which this draft law is being passed, governs the resale of certain second-hand in vitro diagnostic medical devices. This legislative article is in the process of being amended in order to abolish the intervention of an approved body that is responsible for issuing technical certificates prior to the resale of these devices. This amendment forms part of the transposition of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market.

Because several rules apply to both medical devices and in vitro diagnostic medical devices, this draft decree makes references to certain provisions of the draft decree on the resale of second-hand medical devices, which has already been notified to the European Commission (notification 2009/0708). These provisions are intended to specify the documents to be submitted when a device that has never been put into service is resold and the requirements regarding the provision of technical certificates by resellers to purchasers (Article R. 5222-25).

In addition to these references, this draft decree comprises provisions concerning in vitro diagnostic medical devices. Article R. 5222-20 defines the scope of application of the provisions concerning their resale. Article R. 5222-21 is intended to ensure recognition of certificates drawn up by ad hoc bodies in other Member States of the European Union that are party to the Agreement on the European Economic Area. Article R. 5222-22 defines the transfer of second-hand in vitro diagnostic medical devices as the sale of devices “as is”, as opposed to new or refurbished devices, and then sets forth the principle of non-applicability to second-hand devices originating from third countries, which are subject to the rules governing placement on the market as defined by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998. In accordance with Article R. 5222-23, a certificate attests that the device in question has undergone the prescribed maintenance in order to maintain its performances and the required quality controls. It also mentions the date on which it was first put into service, or, if the device has never been put into service, the date when it was initially acquired by the reseller. Article R. 5222-24 sets forth the list of documents that must be provided by the reseller to the purchaser in support of the technical certification that he will have drawn up.

9. Brief Statement of Grounds
The provisions of the Code de la santé publique, which arose out of the transposition of Directive 98/79/EC of 27 October 1998, govern the placing on the market of in vitro diagnostic medical devices, which is understood to mean the sale or giving-away free of charge of new or refurbished devices (Article R. 5221-4, 6°), by making it subject to procedures for the certification of the conformity of devices with essential health and safety requirements (laid down by the directive referred to above) and the prior obtaining of CE marking. However, the resale of second-hand in vitro diagnostic medical devices has not been covered at either the national or community levels. It thus appeared necessary, on health security grounds, to oblige users of sensitive in vitro diagnostic medical devices who resell them to provide evidence that these devices have been properly maintained.

10. Reference Documents - Basic Texts
There are no reference texts

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
TBT aspect

NO – The draft will have no significant effect on international trade.

SPS aspect

NO – The draft will have no significant effect on international trade.

Catherine Day
Secrétaire général
Commission européenne

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