EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2016/378/F

Decree on the summary of characteristics of the medical device

Date received	:	21/07/2016
End of Standstill	:	24/10/2016
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - TRIS/(2016) 02267
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0378/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 - Não 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: 201602267.EN)

1. Structured Information Line
MSG 002 IND 2016 0378 F EN 21-07-2016 F NOTIF

2. Member State
F

3. Department Responsible
Direction générale des entreprises – SQUALPI – Bureau de la réglementation des produits - Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13
d9834.france@finances.gouv.fr
tél : 01 44 97 24 55

3. Originating Department
Ministère des affaires sociales et de la santé.
Direction générale de la santé.
Sous-direction de la politique des produits de santé et de la qualité des pratiques et des soins.

Bureau des dispositifs médicaux et autres produits de santé (PP3).
14, avenue Duquesne - 75350 PARIS 07 SP
catherine.choma@sante.gouv.fr
tél : 01.40.56.68.40 – fax : 01.40.56.47.92

4. Notification Number
2016/0378/F - S10S

5. Title
Decree on the summary of characteristics of the medical device

6. Products Concerned
Biocidal products

7. Notification Under Another Act
-

8. Main Content
The purpose of this decree is to specify the contents of the summary of product characteristics that must be submitted to the competent French authority (French National Agency for the Safety of Medicine and Health Products – ANSM) by manufacturers of class III and implantable medical devices (Article 1 of the decree). Until now, this information has only been submitted by the manufacturer to the notified body. The information to be provided in this summary concerns the identification of the device, its performance and its clinical evaluation (Article 2 of the decree). This information appears in the CE marking application which is made when requesting the certification of conformity that a medical device must also obtain before it is placed on the market.
The way in which this summary of information must be submitted to ANSM is stated in Article 2 of this decree.
The decree shall enter into force six months after it is published in the Official Journal of the French Republic (Article 3).

9. Brief Statement of Grounds
The placing of medical devices on the market came to be regulated at European level at the beginning of the 1990s. Health safety problems such as faulty PIP breast implants have highlighted gaps in current legislation, particularly with regard to class III medical devices and implantable medical devices. For example, the SCENHIR opinion of October 2014 on metal-on-metal hip implants demonstrates the need to carry out enhanced monitoring of the most sensitive implantable medical devices. The competent authorities do not currently have all of the information they need to carry out their market surveillance tasks.
The decree therefore aims to improve market surveillance by providing the competent authorities with the relevant information about the performance and clinical evaluation of class III and implantable medical devices by requiring manufacturers thereof to provide a summary of the characteristics of these devices when declaring to ANSM that they have been put into service in France.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): Article L. 5211-4-1 of the Public Health Code

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 has no significant impact on international trade.

SPS aspect

No - the draft has no significant impact on international trade.

****
European Commission

Contact point Directive (EU) 2015/1535
Fax: +32 229 98043
email: grow-dir83-189-central@ec.europa.eu