



Notification Number: 1993/62/F

Extension of the field of application of the approval procedure for medical equipment

Date received : 24/02/1993
End of Standstill : 26/05/1993 (**26/08/1993**)
Issue of comments by : Commission, Spain
Issue of detailed opinion by : United Kingdom

Message

REP PERMANENTE IRLANDE

REP PERMANENTE GRECE

AGENCE RECHERCHE SCIENTIFIQUE TECHN.
ATT. MME. MOUSTAKA-ZERVAKOU

HELLINIKOS ORG. TYPOPISOOS
ATT. MR. MELAGRAKIS

DEPT. OF TRADE AND INDUSTRY, QUALITY AND EDUCATION DIVISION,
ATT. MR. E. ALLEN

INST INDUST RESEARCH.
ATT. MR. J. NULTY

ICC: PLEASE FORWARD THIS MESSAGE TO ICC MAILBOX EFTBT

TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (93) D/50300/2
DIRECTIVES 83/189/EEC AND 88/182/EEC
TRANSLATION OF TELEX 001
NOTIFICATION 93/0062/F

- 3B2 : 9300333.EN

1. Structured Information Line

TLX 002 IND- 93 0062 F-- EN ----- 930224 --- ---

2. Member State

FRANCE



3. Department Responsible

SECRETARIAT GENERAL DU COMITE INTERMINISTERIEL POUR LES
QUESTIONS DE COOPERATION ECONOMIQUE EUROPEENNE
2 BOULEVARD DIDEROT - 75012 PARIS
DELEGUE INTERMINISTERIEL AUX NORMES
22 RUE MONGE - 75005 PARIS

3. Originating Department

MINISTERE DE LA SANTE ET DE L'ACTION HUMANITAIRE
DIRECTION DES HOPITAUX
SOUS-DIRECTION DES TECHNIQUES HOSPITALIERES ET DES SYSTEMES
D'INFORMATION
BUREAU TI 1 - EQUIPEMENTS ET MATERIELS MEDICAUX

4. Notification Number

93/0062/F

5. Title

Extension of the field of application of the approval
procedure for medical equipment

6. Products Concerned

Internal mammary prostheses

7. Notification Under Another Act

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8. Main Content

Silicon gel, a substance used in the manufacture of mammary
prostheses can have serious consequences on human tissue when
in contact with these prostheses.
It is therefore necessary to check the biocompatibility of
these products.

9. Brief Statement of Grounds

Publication of the text is intended to extend the scope of
approvals to materials which must be provided with absolute
guarantees of safety for patients.

10. Reference Documents - Basic Texts

Article 1. 665-1 of public health law.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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D. WILLIAMSON



EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

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