



Notification Number: 1994/305/F

Draft Decree N° 94 determining the categories for medical devices and their compliance procedures in accordance with Articles L 665-1 to L 665-9 of the Public Health Code.

Date received : 05/10/1994
End of Standstill : 30/12/1994 (30/03/1995)
Issue of comments by : Netherlands
Issue of detailed opinion by : Germany,United Kingdom

Message

REP PERMANENTE ROYAUME UNI

REP PERMANENTE IRLANDE

REP PERMANENTE GRECE

MINISTRY OF INDUSTRY, ENERGY & TECHNOLOGY
ATT. MR. Z.P. MAVROUKAS

HELLINIKOS ORG. TYPOPISOES
ATT. MR. MELAGRAKIS

DGS INTERNATIONAL BELGIUM

DEPT. OF TRADE AND INDUSTRY, QUALITY AND EDUCATION DIVISION,
ATT. MR. K. LAWLESS

INST INDUST RESEARCH.
ATT. MR. J. NULTY

EUROPEAN FREE TRADE ASSOCIATION SURVEILLANCE AUTHORITY
ATT. M. BOHR

EUROPEAN FREE TRADE ASSOCIATION
ATT. MS. MEADEN

TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (94) D/51530/2
DIRECTIVES 83/189/EEC AND 88/182/EEC
TRANSLATION OF TELEX 001
NOTIFICATION 94/0305/F



- 3B1 : 9401530.EN

1. Structured Information Line

TLX 002 IND- 94 0305 F-- EN ----- 941005 --- ---

2. Member State

FRANCE

3. Department Responsible

SECRETARIAT GENERAL DU COMITE INTERMINISTERIEL POUR LES
QUESTIONS DE COOPERATION ECONOMIQUE EUROPEENNE.
2 BD DIDEROT 75012 PARIS.

DELEGATION INTERMINISTERIEL AUX NORMES.
22 RUE MONGE 75005 PARIS

3. Originating Department

MINISTERE DES AFFAIRES SOCIALES, DE LA SANTE ET DE LA VILLE
8 AVENUE DE SEGUR 75007 PARIS.

DIRECTION DES HOPITAUX
DIVISION DES MATERIELS, DES EQUIPEMENTS MEDICAUX ET DES
INNOVATIONS TECHNOLOGIQUES.

4. Notification Number

94/0305/F

5. Title

Draft Decree N° 94 determining the categories for medical
devices and their compliance procedures in accordance with
Articles L 665-1 to L 665-9 of the Public Health Code.

6. Products Concerned

Products referred to: medical devices.

7. Notification Under Another Act

-

8. Main Content

Principal content: amendment of Articles R 5274 to R 5287 of
the Public Health Code concerning approval by the addition of
a mutual recognition clause and a transitional period.

9. Brief Statement of Grounds

Brief reasons: application of a decision during a meeting
held on 29 September 1994 in Brussels with the departments of
Directorate-General 3 - Industry, in liaison with the
representatives of the Secretariat-General of the
Interministerial Committee for Questions of Economic



Co-operation and the Minister for Health., this decision aims to notify the provisions mentioned above in point 8 in order to put an end to the infringements indicated by the European Commission concerning the approval procedure.

10. Reference Documents - Basic Texts

Reference documents - basic texts:

Articles L 665 1 and R 5274 to R 5287 of the Public Health Code concerning approval.

11. Invocation of the Emergency Procedure

No.

12. Grounds for the Emergency

-

D. WILLIAMSON
COMEUR
NNNN