



Notification Number: 1995/199/F

## Draft order supplementing the list of medical appliances subject to approval

Date received : 11/07/1995  
End of Standstill : 13/10/1995 ( 15/01/1996)  
Issue of detailed opinion by : Netherlands,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  
KOMMERSKOLLEGIUM  
ATT. MS. KERSTIN CARLSSON  
MINISTRY OF TRADE AND INDUSTRY  
ATT. MS. TOLONEN  
EUROPEAN FREE TRADE ASSOCIATION SURVEILLANCE AUTHORITY  
ATT. M. BOHR  
EUROPEAN FREE TRADE ASSOCIATION  
ATT. MS. MEADEN  
TELEX 002  
COMMUNICATION FROM THE COMMISSION - SG (95) D/51087/2  
DIRECTIVES 83/189/EEC AND 88/182/EEC



TRANSLATION OF TELEX 001  
NOTIFICATION 95/0199/F

- 3B1 : 9501087.EN

**1. Structured Information Line**

TLX 002 IND- 95 0199 F-- EN ----- 950711 --- ---

**2. Member State**

France

**3. Department Responsible**

Secrétariat Général du Comité Interministériel pour les  
Questions de Coopération Economique Européenne  
2 boulevard Diderot - 75012 PARIS

Délégation Interministérielle aux Normes  
22 rue Monge - 75005 PARIS

**3. Originating Department**

Ministère des Affaires Sociales, de la Santé et de la Ville  
8 avenue de Ségur - 75007 PARIS

Direction des Hôpitaux  
Division des Matériels, des Equipements Médicaux et des  
Innovations Technologiques

**4. Notification Number**

95/0199/F

**5. Title**

Draft order supplementing the list of medical appliances  
subject to approval

**6. Products Concerned**

Medical appliances

**7. Notification Under Another Act**

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**8. Main Content**

Amendment to the list of medical appliances subject to  
approval, provided for by Article R. 5274 of the Public  
Health Code laid down by the orders of 4 February 1991, 23  
January 1992, 10 August 1992 and 23 March 1993.  
- With the exception of homografts, valvular cardiac  
prostheses are subject to approval.

**9. Brief Statement of Grounds**

Analysis of the Björk-Shiley Convexo-Concave cardiac valves  
case demonstrates the need to guarantee the performance and



safety of these appliances prior to their placing on the market, without awaiting entry into force of the compulsory EC marking (14 June 1998) and by using the existing approval procedure. Valves which have obtained the EC marking, may be put on the market without approval.

**10. Reference Documents - Basic Texts**

Articles L. 665-1 to L. 665-9 and R. 5274 to R. 5287 of the Public Health Code concerning the approval of medical appliances.

**11. Invocation of the Emergency Procedure**

NO

**12. Grounds for the Emergency**

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D. WILLIAMSON  
COMEUR  
NNNN