



Notification Number: 1993/18/UK

THE MARKETING OF HEART VALVES IN THE UNITED KINGDOM

Date received : 19/01/1993
End of Standstill : 28/04/1993 (**28/07/1993**)
Issue of detailed opinion by : Commission, France, Netherlands

Message

MINISTERE DE L'INDUSTRIE ET DE LA RECHERCHE
ATT. M. MORTUREUX

SECRET. GENERAL COMITE INTERMINISTERE

INSTITUT BELGE DE NORMALISATION,
ATT. M. CROON

INSPECTION DU TRAVAIL ET DES MINES
VIA MINISTERE DES AFFAIRES ETRANGERES
ATT. M. A. SCHUSTER

MINISTERE DE L'INDUSTRIE
ATT. M. CAVANNA

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

GOVERNMENT SERVICE OF INDUSTRY AND COMMERCE, NSAI
ATT. MR. J. NULTY

MINISTERIE VAN ECONOMISCHE ZAKEN, (DG BEB),
ATT. MR. B. SIEBRING

INDUSTRI- OG HANDELSSTYRELSEN
ATT. MR. KELD DYBKJAER

AGENCE RECHERCHE SCIENTIFIQUE TECHN
ATT. MME. MOUSTAKA-ZERVAKOU

HELLINIKOS ORG. TYPOPISOOS
ATT. MR. MELAGRAKIS

MIN WIRTSCHAFT
ATT. DR. WINKEL



MIN PARA RELACIONES CON LA COMUNIDA
ATT MR. D. ALFREDO RAMBLA JOVANI

MIN INDUSTRIA
ATT MR. ADALBERTO PEREA MARTIN, ESPAGNE

DIRECCIO GERAL QUALIDAD
ATT MR. CANDIDO DOS SANTOS, PORTUGAL

DGS INTERNATIONAL BELGIUM

REP PERMANENTE ROYAUME UNI

REP PERMANENTE IRLANDE

REP PERMANENTE GRECE

ICC: PLEASE FORWARD THIS MESSAGE TO ICC MAILBOX EFTBT

TELEX 001

COMMUNICATION FROM THE COMMISSION - SG (93) D/50071
DIRECTIVES 83/189/EEC AND 88/182/EEC

NOTIFIKATION - NOTIFIZIERUNG - NOTIFICATION - NOTIFICACION
NOTIFICATION - NOTIFICA - KENNISGEVING - NOTIFICACAO 93/0018/UK

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1. Structured Information Line

TLX 001 IND- 93 0018 UK- EN ----- 930119 --- ---

2. Member State

UNITED KINGDOM

3. Department Responsible

DEPARTMENT OF TRADE AND INDUSTRY: STANDARDS, QUALITY AND
POLICY UNIT

3. Originating Department

DEPARTMENT OF HEALTH/MEDICAL DEVICES DIRECTORATE

4. Notification Number

93/0018/UK

5. Title



THE MARKETING OF HEART VALVES IN THE UNITED KINGDOM

6. Products Concerned

HEART VALVE PROSTHESES

7. Notification Under Another Act

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8. Main Content

THE DOCUMENT PROVIDES GUIDANCE ON PARTICULAR ASPECTS OF THE MANUFACTURE, TESTING AND POST-MARKET SURVEILLANCE OF HEART VALVE PROSTHESES.

THE GUIDANCE IS INTENDED TO ASSIST MANUFACTURERS BY CLARIFYING THE DEPARTMENT OF HEALTH'S VIEWS ON THE MINIMUM MEASURES CONSIDERED APPROPRIATE FOR ENSURING THE SAFETY OF HEART VALVE PROSTHESES IN HUMAN SUBJECTS.

THE DOCUMENT WAS PREPARED IN CONSULTATION WITH SEVERAL MANUFACTURERS OF THESE PRODUCTS.

THE DOCUMENT HAS NO LEGAL STATUS.

9. Brief Statement of Grounds

THE SAFETY AND LONG TERM RELIABILITY OF HEART VALVE PROSTHESES HAS BEEN THE SUBJECT OF MUCH PUBLICITY IN RECENT YEARS.

IN THE UNITED KINGDOM THERE IS NO SPECIFIC LEGISLATION CONCERNING THESE PRODUCTS AND CONTROL IS ON A VOLUNTARY BASIS.

THE GUIDANCE BRINGS TOGETHER ADVICE THAT HAS BEEN GIVEN TO MANUFACTURERS ON AN INFORMAL BASIS, SO THAT THE UNITED KINGDOM CAN SEEK THEIR CO-OPERATION IN ENSURING MINIMUM SAFETY STANDARDS ARE MET.

10. Reference Documents - Basic Texts

DRAFT DOCUMENT:

THE MARKETING OF HEART VALVES IN THE UNITED KINGDOM

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

COMEUR
NNNN