Notification Number: 1993/19/UK

ANIMAL TISSUES IN MEDICAL DEVICES: GUIDANCE ON THE CONTROL OF SOURCE MATERIALS, AND THE VALIDATION AND ROUTINE CONTROL OF CHEMICAL METHODS USED FOR STERILISATION

Date received	:	19/01/1993
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Message

MINISTERE DE L'INDUSTRIE ET DE LA RECHERCHE
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SECRET. GENERAL COMITE INTERMINISTERE

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ATT. M. CROON

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VIA MINISTERE DES AFFAIRES ETRANGERES
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DEPT. OF TRADE AND INDUSTRY, QUALITY AND EDUCATION DIVISION,
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MINISTERIE VAN ECONOMISCHE ZAKEN, (DG BEB),
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ATT. MR. KELD DYBKJAER

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HELLINIKOS ORG. TYPOPISEOS
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/50072
DIRECTIVES 83/189/EEC AND 88/182/EEC

NOTIFIKATION - NOTIFIZIERUNG - NOTIFICATION - NOTIFICACION
NOTIFICATION - NOTIFICA - KENNISGEVING - NOTIFICACAO 93/0019/UK

FRISTERNE INDLEDES IKKE -KEIN FRISTBEGINN - DOES NOT OPEN THE DELAYS - NO ABRE EL PLAZO - N'OUVRE PAS DE DELAIS - NON FA DECORRERE LA MORA - GEEN TERMIJNBEGIN - NAO INICIA O PRAZO

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1. Structured Information Line
TLX 001 IND- 93 0019 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

93/0019/UK

5. Title
ANIMAL TISSUES IN MEDICAL DEVICES:
GUIDANCE ON THE CONTROL OF SOURCE MATERIALS, AND THE VALIDATION AND ROUTINE CONTROL OF CHEMICAL METHODS USED FOR STERILISATION

6. Products Concerned
MEDICAL DEVICES INCORPORATING OR CONTAINING MATERIALS OF ANIMAL ORIGIN

7. Notification Under Another Act
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8. Main Content
THE DOCUMENT PROVIDES GUIDANCE ON PARTICULAR ASPECTS OF THE QUALITY ASSURANCE OF MEDICAL DEVICES WHICH CONTAIN ANIMAL TISSUES.
IT IS INTENDED TO ASSIST MANUFACTURERS IN IMPLEMENTING AN EFFECTIVE QUALITY ASSURANCE SYSTEM FOR THE CONTROL OF SOURCE MATERIALS AND THE VALIDATION AND ROUTINE CONTROL OF THE STERILIZATION PROCESS FOR SUCH DEVICES.
THE DOCUMENT HAS NO STATUTORY FORCE.
THE PROVISIONS OF EC GUIDELINES PREPARED FOR MEDICINAL PRODUCTS HAVE BEEN USED AS A BASIS FOR MUCH OF THE TEXT.

9. Brief Statement of Grounds
THERE ARE CURRENTLY NO NATIONAL OR INTERNATIONAL GUIDELINES COVERING THESE PARTICULAR QUALITY ASSURANCE ASPECTS FOR MEDICAL DEVICES. THE CURRENT SYSTEMS FOR THE ASSESSMENT OF QUALITY ASSURANCE OF MEDICAL DEVICE MANUFACTURES WOULD BE SUPPORTED BY THE PUBLICATION OF THESE GUIDELINES.

10. Reference Documents - Basic Texts
DRAFT DOCUMENT:
ANIMAL TISSUES IN MEDICAL DEVICES: GUIDANCE ON THE CONTROL OF SOURCE MATERIALS, AND THE VALIDATION AND ROUTINE CONTROL OF CHEMICAL METHODS USED FOR STERILIZATION.

11. Invocation of the Emergency Procedure
NO

12. Grounds for the Emergency
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D. WILLIAMSON
COMEUR
NNNN