STATUTORY INSTRUMENTS

1963 No. 1458

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Surgical Materials) Regulations 1963

Made - - - -	23*rd August* 1963
Laid before Parliament	2*nd September* 1963
Coming into Operation	16*th September* 1963

The Joint Committee constituted by section 4(1) of the Therapeutic Substances Act 1956(a), in exercise of the powers conferred on them by sections 1 and 5 of the said Act, after consultation with the Advisory Committee constituted under section 4(2) of the said Act, hereby make the following regulations:—

PART I

PRELIMINARY

Citation

1. These regulations may be cited as the Therapeutic Substances (Manufacture of Surgical Materials) Regulations 1963 and shall come into operation on 16th September 1963.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—

"the Act" means the Therapeutic Substances Act 1956;

"the general regulations" means the Therapeutic Substances (Manufacture and Importation) General Regulations 1963(b);

"the licensing authority" has the same meaning as in the general regulations.

(2) Any reference in these regulations to any provision of the general regulations shall be construed as a reference to that provision as amended, extended or re-enacted by any subsequent regulations made under Part I of the Act.

(3) The Interpretation Act 1889(c) applies to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

Inclusion of substances in schedule to Act

3. Notwithstanding the revocation by the general regulations of the Therapeutic Substances Regulations 1952(d) and the Therapeutic Substances Amendment Regulations 1957(e), the surgical materials to which these regulations relate shall continue to be included in schedule 1 to the Act.

(a) 4 & 5 Eliz. 2. c. 25. (b) S.I. 1963/1450 (1963 II, p. 2483). (c) 52 & 53 Vict. c. 63.
(d) S.I. 1952/1937 (1952 III, p. 3420). (e) S.I. 1957/550 (1957 II, p. 2553).

Scope of regulations

4. These regulations relate to—

(*a*) surgical ligature and surgical suture; and

(*b*) any absorbent or protective material capable of being absorbed by the body tissues;

which are offered or intended to be offered for sale for use in surgical operations upon the human body.

PART II

GENERAL PROVISIONS APPLICABLE TO SURGICAL MATERIALS

Method of sterilisation

5. The substances to which these regulations relate shall be sterilised by a method approved by the licensing authority.

Tests for sterility

6.—(1) The substances to which these regulations relate shall be tested for sterility in accordance with the general regulations:

Provided that paragraph 2(4) of schedule 2 to those regulations shall apply with the modification that the expression " 12 days " shall be substituted for the expression " 5 days ".

(2) The tests described in the said schedule as so applied shall be applied to the whole of the material in the containers:

Provided that in the case of the materials to which parts IV to VI of these regulations relate, the tests may be applied to a portion of the material in the container if the licensing authority approves a method of so applying them.

(3) In the case of the materials to which parts III to VI of these regulations relate, if any growth of micro-organisms is found during the period of the test, a further sample may be taken from the batch in the proportions specified in paragraph 1(2) of the said schedule 2, and the tests may be repeated on the sample so taken. If on examination of the further sample no micro-organisms is found, the batch shall be regarded as having passed the test; but if on such further examination any growth of micro-organisms is found the batch from which the sample was taken shall not be issued.

Labelling

7.—(1) The particulars specified in regulation 6(1)(*a*), (*b*) and (*c*) of the general regulations shall be borne by the container of any such material.

(2) The particulars specified in sub-paragraphs (*e*) and (*i*) of the said regulation 6(1) shall be borne either by the container of any such material or by the package in which the material is offered for sale.

PART III

SPECIAL PROVISIONS APPLICABLE TO SURGICAL LIGATURE AND SURGICAL SUTURE

Definition and proper name

8. Surgical ligature or surgical suture is any ligature or form of binding material prepared from the gut or any tissue of an animal. When such ligature or suture is offered or intended to be offered for sale as sterile and ready for use, the proper name of the substance shall be " sterilised surgical ligature " or " sterilised surgical suture " followed, in brackets, by the accepted scientific name or a title descriptive of the true nature and origin of the substance, as, for example, " sterilised surgical ligature (catgut) " or " sterilised surgical suture (horsehair) ".

Quality

9. Every batch of sterilised surgical ligature or surgical suture shall consist entirely of material which has been either simultaneously, or during any period specified by the licensing authority, subjected to the same process or series of processes for rendering it sterile.

Labelling

10. Any particulars which in pursuance of regulation 6 of these regulations are borne by the container of surgical ligature or surgical suture shall either be indelibly marked on the body of the container or be indelibly marked or perforated on a label enclosed in the container and readily legible without opening the container.

PART IV

SPECIAL PROVISIONS APPLICABLE TO ABSORBABLE GELATIN

Definition and proper names

11. Absorbable gelatin is gelatin prepared in the form of a finely porous sponge-like material or of a film. It may contain a bacteriostatic or other antibacterial agent. Its proper name is "absorbable gelatin sponge" or "absorbable gelatin film", as the case may be.

PART V

SPECIAL PROVISIONS APPLICABLE TO OXIDISED CELLULOSE

Definition and proper name

12. Oxidised cellulose is a polyanhydroglucuronic acid obtainable by the nitrogen dioxide oxidation of surgical gauze or cotton. Its proper name is "oxidised cellulose", followed by a word or words approved by the licensing authority as descriptive of the form of the material.

PART VI

SPECIAL PROVISIONS APPLICABLE TO CALCIUM ALGINATE

Definition and proper name

13. Calcium alginate consists of the calcium salt or the mixed calcium and sodium salt of alginic acid (which is a polyuronic acid composed of residues of D-mannuronic acid) and is prepared in the form of gauze or wool. Its proper name is "calcium alginate" followed by a word or words approved by the licensing authority as descriptive of the form of the material.

These regulations were made by the aforesaid Joint Committee on 23rd August 1963.

J. Enoch Powell,
Michael Noble,
Wm. J. Morgan,
Members of the Joint Committee.

B. H. Betts,
Clerk to the Joint Committee.

EXPLANATORY NOTE

(This Note is not part of the Regulations, but is intended to indicate their general purport.)

These regulations, made under Part I of the Therapeutic Substances Act 1956, form part of a comprehensive code relating to the manufacture and importation of therapeutic substances and are to be read in conjunction with the Therapeutic Substances (Manufacture and Importation) General Regulations 1963.

These regulations consolidate with minor amendments those requirements of the Therapeutic Substances Regulations 1952 to 1957 which apply to surgical ligature and suture and to certain other substances used in surgical operations on the human body. The regulations prescribe requirements as to :—

(*a*) methods of sterilisation ;

(*b*) tests for sterility ;

(*c*) quality ; and

(*d*) labelling.