INTERNATIONAL STANDARD

ISO
6018
First edition
1987-11-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Orthopaedic implants — General requirements for marking, packaging and labelling

Implants orthopédiques — Conditions générales pour le marquage, l'emballage et l'étiquetage

Reference number
ISO 6018 : 1987 (E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 6018 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Printed in Switzerland

Orthopaedic implants — General requirements for marking, packaging and labelling

1 Scope and field of application

This International Standard specifies general requirements for the marking, packaging and labelling of orthopaedic implants supplied either sterile or as manufactured, i.e. prior to sterilization.

NOTE — The requirements of an International Standard for a particular implant take precedence over the requirements of this International Standard.

2 Reference

ISO 2014, *Writing of calendar dates in all-numeric form.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 sterile: In microbiology, free from all living organisms; in practice, the condition of a product that has been subjected to a validated sterilization process and maintained in this state by suitable protection.

3.2 sterilized: Term used to denote an object that has been subjected to a validated sterilization process.

3.3 unit: Individual device(s) or object(s) defined in the relevant product standard or regulation.

3.4 kit: A number of components to be used for a single purpose on the same occasion.

3.5 unit pack: A pack containing a single unit or kit.

3.6 multiple pack: A pack containing a number of unit packs.

3.7 sterile pack: A pack intended to maintain the sterility of the contents and comprising an inner and outer container.

3.8 inner container: The packaging that is in direct contact with the implant.

3.9 outer container: The packaging that envelops the inner container such that sterility and the integrity of the contents are maintained.

4 Identification marking of orthopaedic implants

4.1 General

Each implant shall be identified by means of the information listed in 4.2 and in accordance with the requirements specified in 4.3.

4.2 Marking

The identification marking of the implant shall comprise the following information (see, however, 4.3.2):

a) the name or trade-mark of the manufacturer or supplier;

b) the designation of the material, comprising either the full reference of the relevant International Standard(s) (if available) for the material, or the relevant symbol;

NOTES

1 If a relevant International Standard is not available, an equivalent national standard may be used.

2 The following symbols have been agreed for use in conjunction with metallic materials:

S — stainless steel;

T — titanium and its alloys;

C — cobalt-based alloys.

c) the manufacturer's traceability code for the implant;

d) the designated size and type, if applicable.

4.3 Application of marking

4.3.1 If not excluded by the relevant International Standard(s) for a particular implant, implants shall be marked with the information listed in 4.2 in characters not less than 1 mm high (see, however, 4.3.2).