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Non-active surgical implants — General requirements

Implants chirurgicaux non actifs — Exigences générales

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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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14630 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This fourth edition cancels and replaces the third edition (ISO 14630:2008), which has been technically revised.

Introduction

This International Standard provides a method of addressing the fundamental principles outlined in ISO/TR 14283 as they apply to non-active surgical implants. It also provides a method for demonstrating compliance with the relevant essential requirements as outlined in the general terms in Annex 1 of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as they apply to non-active surgical implants, hereafter referred to as implants. It might also help manufacturers comply with the requirements of other regulatory bodies.

There are three levels of standards dealing with non-active surgical implants and related instrumentation. For the implants themselves, they are as follows, with level 1 being the highest.

— Level 1: General requirements for non-active surgical implants.

— Level 2: Particular requirements for families of non-active surgical implants.

— Level 3: Specific requirements for types of non-active surgical implants.

Level 1 standards, such as this International Standard and Reference [4], contain requirements that apply to all non-active surgical implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards (see References [5], [6], [7], [8] and [9]) apply to a more restricted set or family of non-active surgical implants, such as those designed for use in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards (see References [10], [11], [12] and [13]) apply to specific types of implants within a family of non-active surgical implants, such as hip joints or arterial stents.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

NOTE The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.