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Implants for surgery — Essential principles of safety and performance

Implants chirurgicaux — Principes essentiels de la sécurité et les performances

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

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This third edition cancels and replaces the second edition (ISO/TR 14283:2004), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the previous edition was based on Annex I of the European Council Medical Devices Directive, while this edition is based on guidance documents developed by the Global Harmonisation Task Force (GHTF).

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Introduction

The purpose of this document is to harmonize the documentation and procedures that are used to assess whether an implant conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by regulatory authorities , conformity assessment bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of implants in the interest of public health. It seeks to strike a balance between the responsibilities of regulatory authorities to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry.

A further purpose is to provide a basis for the development of technical standards for implants intended to have international applicability.

This document describes fundamental design and manufacturing requirements, referred to as "Essential Principles of Safety and Performance" that, when met, indicate an implant is safe and performs to its specification.

This document is derived and adapted from the previous version of this document (2004) and from guidance documents developed by the Global Harmonization Task Force (GHTF) (GHTF/SG 1 documents N55,[3] N68,[4] N70[5] and N71[6]). In a few cases additional guidance has been provided and in these cases the additional guidance has been clearly identified by means of a Note.

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Annex A lists applicable pre-existing national or regional requirements, which can be consulted for comparison with the Essential Principles contained in this report.

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The Bibliography provides a list of references that can be used to link these essential principles to standards and guidance documents giving product related requirements and guidance on the analysis of risks associated with the use of implants.

NOTE The GHTF documents listed in the Bibliography are subject to periodic review and can be superseded by later documents. The reader is encouraged to refer to the International Medical Device Regulators Forum (IMDRF) website at http://www.imdrf.org/documents/documents.asp to confirm whether the referenced documents remain current.

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Implants for surgery — Essential principles of safety and performance

1 Scope

This document provides fundamental principles for the design and manufacture of active or non-active implants in order that each implant can achieve its intended purpose.

It is often the case that instruments and other equipment are used in association with implants. These devices might be useful or even essential for the safe implantation and/or use of the implants. This document applies to implants, however, it also applies to associated instruments and equipment to the extent that the design and manufacture of the implants is intended to ensure the safe combination and use of the implants with such devices.

Requirements for the safe operation and use of associated instruments and equipment are contained in other standards.

2 Normative references

There are no normative references in this document.

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3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
active implant
implant whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy

Note 1 to entry: Implants intended to transmit energy, substances or other elements between an active implant and the patient, without any significant change, are not considered to be active implants.

3.2
clinical data
safety and/or performance information that are generated from the clinical use of a medical device

[SOURCE: GHTF/SG1/N68:2012, 4.0]

3.3
clinical evaluation
assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

[SOURCE: GHTF/SG1/N68:2012, 4.0]

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3.4
clinical investigation
systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device

[SOURCE: GHTF/SG1/N70:2011, 4.0]

3.5
harm
physical injury or damage to the health of people or damage to property or the environment

[SOURCE: GHTF/SG1/N68:2012, 4.0]

3.6
hazard
potential source of harm

[SOURCE: GHTF/SG1/N68:2012, 4.0]

3.7
implant
medical device which is intended

— to be totally introduced into the human body, or

— to replace an epithelial surface or the surface of the eye

by surgical or clinical intervention, and which is intended to remain in place after the procedure

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Note 1 to entry: Any medical device intended to be partially introduced into the human body through surgical or clinical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implant.

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3.8
information supplied by the manufacturer
see *labelling* (3.12)

3.9
instructions for use
information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken

[SOURCE: GHTF/SG1/N70:2011, 4.0]

3.10
intended use
intended purpose
use or purpose for which the implant or medical device is intended as indicated in the product specifications, instructions and information provided by the manufacturer

[SOURCE: GHTF/SG1/N68:2012, 4.0, modified — "the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the" has been replaced by "use or purpose for which the implant or medical device is intended as indicated in the product".]

3.11
label
written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices

[SOURCE: GHTF/SG1/N70:2011, 4.0]

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3.12
labelling
label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

[SOURCE: GHTF/SG1/N70:2011, 4.0]

3.13
manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)
Note 1 to entry: The term "person" that appears here includes legal entities such as a corporation, a partnership or an association.

[SOURCE: GHTF/SG1/N055:2009, 5.1, modified.]

3.14
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

[SOURCE: GHTF/SG1/N71:2012, 5.1, modified — A note on products which might be considered to be medical devices in some jurisdictions but not in others has been deleted.]

3.15
regulatory authority
government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that implants marketed within its jurisdiction comply with legal requirements

[SOURCE: GHTF/SG1/N68:2012, 4.0, modified — the abbreviation "RA" has been deleted.]

3.16
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: GHTF/SG1/N68:2012, 4.0]

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4 Application of essential principles

A manufacturer of an implant is expected to design and manufacture a product that is safe and performs as intended. This document describes fundamental principles for design and manufacturing, referred to as "Essential Principles of Safety and Performance", to ensure this outcome.

It is the manufacturer's responsibility to demonstrate conformity of the implant to all the applicable essential principles. If for a particular implant some essential principles are considered to be not applicable, then it is the manufacturer's responsibility to document the reason for excluding these essential principles.

5 Essential principles applicable to implants

5.1 General

5.1.1 Implants must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which can be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

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5.1.2 The solutions adopted by the manufacturer for the design and manufacture of the implants must conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer must control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer must apply the following principles in the priority order listed:

— identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;

— eliminate risks as far as reasonably practicable through inherently safe design and manufacture;

— reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and

— inform users of any residual risks.

5.1.3 Implants must achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.

5.1.4 The characteristics and performances referred to in 5.1.1, 5.1.2 and 5.1.3 must not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the implant, as indicated by the manufacturer, when the implant is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

5.1.5 Implants must be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

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5.1.6 All known and foreseeable risks, and any undesirable effects, must be minimised and be acceptable when weighed against the benefits of the intended performance of implants during normal conditions of use.

5.2 Chemical, physical and biological properties

5.2.1 The implants must be designed and manufactured in such a way as to ensure the characteristics and performance referred to in 5.1. Particular attention must be paid to:

— the choice of materials used, particularly as regards toxicity and where applicable flammability,

— the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device,

— the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.

NOTE Further information is provided in ISO 10993-1.

5.2.2 The implants must be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the implants and to patients, taking account of the intended purpose of the implant. Particular attention must be paid to tissues exposed and to the duration and frequency of exposure.

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5.2.3 The implants must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the implants are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

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5.2.4 The implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that can leach or leak from the implant. Special attention must be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

5.2.5 The **i**mplants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the implant taking into account the implant and the nature of the environment in which it is intended to be used.

5.2.6 The **i**mplants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by insufficient cleanliness of the implant. Risks posed by insufficient cleanliness include risks posed by bacterial endotoxins, pyrogens and particulate contaminates.

NOTE The principle in 5.2.6 has been added to the ones in the previous edition, and to the information given in Global Harmonization Task Force guidance documents.

5.3 Infection and microbial contamination

5.3.1 The implants and manufacturing processes must be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design must:

— allow easy handling, and, where necessary:

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