TECHNICAL REPORT

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Implants for surgery — Fundamental principles

Implants chirurgicaux — Principes fondamentaux

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Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Terms and definitions 1

3 General principles 2

4 Specific principles regarding design and construction 3
4.1 Chemical, physical and biological properties 3
4.2 Infection and microbial contamination 4
4.3 Construction and environmental properties 4
4.4 Implants with a measuring function 5
4.5 Protection against radiation 5
4.5.1 General 5
4.5.2 Intended radiation 5
4.5.3 Unintended radiation 5
4.5.4 Instructions 5
4.6 Ionizing radiation 6
4.7 Principles for implants connected to or equipped with an energy source 6
4.7.1 General 6
4.7.2 Protection against electrical risks 6
4.7.3 Protection against mechanical risks 6
4.7.4 Protection against the risks posed to the patient by energy supplies or substances 7
4.8 Information supplied by the manufacturer 7
4.9 Clinical evaluation 9

Annex A (informative) **Correspondence to some regulatory documents** 10
A.1 General 10
A.2 European Economic Area 10
A.3 Australia 10
A.4 Canada 10
A.5 China 11
A.6 Japan 11

Bibliography 15

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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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/TR 14283 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This second edition cancels and replaces the first edition (ISO/TR 14283:1995), the annex of which has been updated.

Introduction

Requirements on the design, manufacture and performance of implantable medical devices are developing in various ways in different countries and international regions. As the medical device industry is already active on a global basis, and is becoming more so, concern is growing as to the need for international and mutually recognized standards for the design and performance of such devices.

In order for standards and legal or regulatory requirements to be compatible, they both need to be based on an understanding of the fundamental principles applicable to the implants. This Technical Report presents a compilation of these principles. The structure of this report is derived and adapted from the Essential Requirements given in the European Council Medical Device Directives.

This Technical Report is, by its nature, purely informative.

When balancing risk and benefit to the patients, it is good practice to subject implants to a risk analysis and this is implicit in this Technical Report. However, risk analysis cannot always identify all risks. Such uncertainty may be acceptable in the light of perceived benefits to the patient. Follow-up performance review can provide information to confirm the acceptability of the risk.

The correspondence of the fundamental principles contained in this Technical Report with pre-existing national and/or regional requirements is contained in Annex A. The bibliography provides a list of standards that may be used to link these fundamental principles to standards giving product related requirements and guidance on the analysis of risks associated with the use of implants.

NOTE 1 This report is intended to be a basis for harmonized standards, but it is recognized that specific wording may be at variance with wording or definitions used in existing national documents, particularly in areas related to “lifetime”, “intended use”, “normal conditions of use”, etc.

NOTE 2 Should standards based on this Technical Report be recognized by national authorities having responsibility for approval for commercialization of such devices in their respective countries, the opportunity exists for the rationalization and harmonization of such approval activities. The consequent overall cost reduction is to the benefit of all parties, particularly patients, health care providers, insurers and industry.

Implants for surgery — Fundamental principles

1 Scope

This Technical Report provides fundamental principles for the design and manufacture of active or non-active implants in order to achieve the intended purpose.

2 Terms and definitions

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

2.1
accessory
article which, while not being a medical device, is intended specifically by its manufacturer to be used together with a device to enable the device to be used as intended by its manufacturer

2.2
active medical device
any medical device 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 Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

2.3
intended purpose
use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials

2.4
labelling
all written, printed or graphic matter

— affixed to a medical device or any of its containers or wrappers, or

— accompanying a medical device

relating to identification, technical description, and use of the medical device, but excluding shipping documents

NOTE Some regional and national regulations refer to “labelling” as “information supplied by the manufacturer”.

[ISO 13485:2003]

2.5
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his/her own name, regardless of whether these operations are carried out by that person him-/herself or on his/her behalf by a third party

2.6
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

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

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

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

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

NOTE Adapted from ISO 13485:2003.

2.7
medicinal product
any substance or combination of substances presented for treating or preventing disease in human beings or animals with a view to making a medical diagnosis, or for restoring, correcting or modifying physiological functions in human beings or in animals

2.8
surgical implant
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 intervention, and which is intended to remain in place after the procedure

NOTE Any medical device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered a surgical implant.

3 General principles

3.1 The implants should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will 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 may 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.

3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform to safety principles, taking into account the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order:

a) eliminate or reduce risks as far as possible (inherently safe design and construction);

b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;

c) inform users of the residual risks due to any shortcomings of the protection measures adopted.

3.3 The implants should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in 3.1, as specified by the manufacturer.

3.4 When the implant is subjected to stresses which can occur during normal conditions of use, the characteristics and performances referred to in 3.1, 3.2 and 3.3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the implant as indicated by the manufacturer.

3.5 The implants should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage when taking into account the instructions and information provided by the manufacturer.

3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.

4 Specific principles regarding design and construction

4.1 Chemical, physical and biological properties

4.1.1 The implants should be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Clause 3 on general principles. Particular attention should be paid to

a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,

b) the compatibility between the materials used and biological tissues, cells and body fluids, taking into account the intended purpose of the implant.

4.1.2 The implants should be designed, manufactured and packed 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 the patients, taking into account the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.

4.1.3 The implants should 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 should 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 such that their performance is maintained in accordance with the intended use.

4.1.4 If an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in 2.7 and which is liable to act upon the body with action ancillary to that of the implant, the safety, quality and usefulness of the substance should be verified, taking into account the intended purpose of the implant.

4.1.5 The implants should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the implant.

4.1.6 Implants should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the implant, taking into account the implant and the nature of the environment in which it is intended to be used.

4.1.7 Implants should be designed and manufactured in such a way as to minimize the risks to the patient or user by the programming and control systems, including software.

4.2 Infection and microbial contamination

4.2.1 The implants and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design should allow easy handling and, where necessary, minimize contamination of the implant by the patient, or vice versa, during use.

4.2.2 Tissues of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

Information on the geographical origin of the animals should be retained by the manufacturer.

Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal security. In particular, safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

4.2.3 Implants delivered in a sterile state should be designed, manufactured and packed in protective packaging which provides a microbial barrier to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions stipulated by the manufacturer, until the protective packaging is damaged or opened.

4.2.4 Implants delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.

4.2.5 Implants intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

4.2.6 Packaging systems for non-sterile implants should keep the product without deterioration at the level of cleanliness stipulated and, if the implants are to be sterilized prior to use, minimize the risk of microbial contamination. The packaging system should be suitable, taking into account the method of sterilization indicated by the manufacturer.

4.2.7 The packaging and/or label of the implant should distinguish between identical or similar products sold in both sterile and non-sterile conditions.

4.3 Construction and environmental properties

4.3.1 If the implant is intended for use in combination with other devices or equipment, the whole combination, including the connection system, should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.

4.3.2 Implants should be designed and manufactured in such a way as to remove or minimize, as far as possible, the following:

a) risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,

b) risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,

c) risks of reciprocal interference with other devices (such as defibrillators or high-frequency surgical equipment) normally used in the investigations or for the treatment given,

d) risks which may arise where maintenance and calibration are impossible, including (if applicable)

   — excessive increase of leakage currents,

— ageing of materials used,

— excess heat generated by the implant,

— decreased accuracy of any measuring or control mechanism.

4.3.3 Implants should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal conditions and fault conditions. By “risks during normal conditions and fault conditions” are meant those risks which have been determined by a risk analysis. Particular attention should be paid to implants whose intended use includes exposure to flammable substances or to substances which could cause combustion.

4.4 Implants with a measuring function

4.4.1 Implants with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy and stability, within appropriate limits of accuracy and taking into account the intended purpose of the implant. The limits of accuracy should be indicated by the manufacturer.

4.4.1.1 The measurements, monitoring and display scale should be designed in accordance with ergonomic principles, taking into account the intended purpose of the implant.

4.4.1.2 If an implant or its accessories bears instructions required for the operation of the implant or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31 series.

4.5 Protection against radiation

4.5.1 General

Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation is reduced as low as possible, compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

4.5.2 Intended radiation

4.5.2.1 If implants are designed to emit hazardous levels of radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission, the implants should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

4.5.2.2 If implants are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

4.5.3 Unintended radiation

Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.

4.5.4 Instructions

The operating instructions for implants emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user, and ways to avoid misuse and eliminate the risks inherent in use.

4.6 Ionizing radiation

4.6.1 Implants intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.

4.6.2 Implants emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose while minimizing radiation exposure of the patient and user.

4.6.3 Implants emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose.

4.7 Principles for implants connected to or equipped with an energy source

4.7.1 General

4.7.1.1 Implants incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of risks (of the system) as determined by a risk analysis for the particular device/system, appropriate means should be adopted to eliminate or reduce as far as possible their risk.

4.7.1.2 Implants for which the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.

4.7.1.3 Implants should bear, if practical and appropriate, a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of implant). It should be possible to read this code, if necessary, without the need for a surgical operation.

4.7.1.4 For implants for which the safety of the patients depends on an external power supply, the external power supply should include an alarm system to signal any power failure.

4.7.1.5 External devices intended to monitor one or more clinical parameters from an implant should be equipped with appropriate alarm systems to alert the user to situations which could lead to death or severe deterioration of the patient's state of health.

4.7.2 Protection against electrical risks

4.7.2.1 Implants should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal conditions and fault conditions provided the implants are installed correctly. By the “risks during normal conditions and fault conditions” are meant those risks which have been determined by a risk analysis for the particular device(s).

4.7.2.2 Active implants should be designed and manufactured in such a way as to minimize the risks connected with the use of energy sources, with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices.

4.7.3 Protection against mechanical risks

4.7.3.1 Implants should be designed and manufactured in such a way as to protect the patient and user against mechanical risks, for example those connected with resistance, stability and moving parts.

4.7.3.2 Implants should be designed and manufactured in such a way as to minimize the risks arising from vibration generated by the implants, taking into account technical progress and the means available for limiting vibration, particularly at source, unless the vibrations are part of the specified performance.

4.7.3.3 Implants should be designed and manufactured in such a way as to minimize the risks arising from the noise emitted, taking into account technical progress and the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

4.7.3.4 Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.

4.7.4 Protection against the risks posed to the patient by energy supplies or substances

4.7.4.1 Implants should be designed and constructed in such a way that the proper functioning of the programming and control systems, including software, do not jeopardize the safety of the patient and of the user, taking into account the intended use.

4.7.4.2 Implants designed to supply energy or administer medicinal substances should be designed and constructed in such a way that the flowrate can be set and maintained accurately enough to minimize the risk to the patient.

4.7.4.3 Implants designed to administer medicinal products should incorporate suitable means to prevent and/or indicate any inadequacies in the flowrate that could pose a danger.

4.7.4.4 Implants designed to supply energy or administer medicinal substances should be designed and constructed so that suitable means are incorporated to minimize the risk of accidental release of dangerous levels of energy or the medicinal substance.

4.8 Information supplied by the manufacturer

4.8.1 Each implant should be accompanied by the information needed to use it safely and to identify the manufacturer, taking into account the training and knowledge of the potential users.

This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the implant safely should be set out on the implant itself and/or on the packaging for each unit or, if appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information should be set out in the leaflet supplied with one or more implants.

Instructions for use should be included in the packaging for every implant.

4.8.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to International Standards. If no standards exist, the symbols and colours should be described in the documentation supplied with the implant.

4.8.3 The label should bear the following particulars:

a) the name or trade name and address of the manufacturer;

b) the details strictly necessary for the user to identify the implant and the contents of the packaging;

c) where appropriate, an indication that the contents of the packaging are sterile;

EXAMPLE “STERILE”

d) where appropriate, the batch code or the serial number (SN), preceded by an appropriate identification;

EXAMPLE “LOT” or “SN” respectively

e) where appropriate, an indication of the date by which the implant should be used;

f) an indication that the implant is for single use;

g) if appropriate, any indication of special purpose (e.g. “custom-made device” or “exclusively for clinical investigations”);

h) any special storage and/or handling conditions;

i) any special operating instructions;

j) any warnings and/or precautions to take;

k) for active implants, month and year of manufacture;

l) if applicable, method of sterilization.

4.8.4 If the intended purpose of the implant is not obvious to the user, the manufacturer should clearly state it on the label and in the instructions for use.

4.8.5 Wherever reasonable and practicable, the implants and detachable components should be identified, if appropriate in terms of serial numbers or batches, to allow all appropriate actions to be taken following discovery of any potential risk posed by the implants and detachable components.

4.8.6 If appropriate, the instructions for use should contain the following particulars:

a) the details referred to in 4.8.3, with the exception of d), e) and k);

b) the performances referred to in 3.3 and any undesirable side effects;

c) if the implant should be used with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct implants or equipment to use in order to obtain a safe combination;

d) all the information needed to verify whether the implant is properly used and can operate correctly and safely, plus, where appropriate, information allowing the lifetime of the energy source to be established;

e) where appropriate, information to avoid specified risks in connection with implantation of the implant;

f) information regarding the risks of reciprocal interference posed by the presence of the implant during specific investigations or treatment;

g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

h) if implants are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the implant will still comply with the principles in Clause 3;

i) details of any further treatment or handling needed before the implant can be used;

EXAMPLE Sterilization, final assembly, etc.

j) in the case of implants emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

The instructions for use should also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

k) precautions to be taken in the event of changes in the performance of the implant;

l) precautions to be taken as regards exposure to, in reasonably foreseeable environmental conditions, e.g. to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

m) adequate information regarding the medicinal product or products which the implant in question is designed to administer, including any limitations in the choice of substances to be delivered;

n) precautions to be taken against any special, unusual risks related to the disposal of the implant;

o) medicinal products incorporated into the implant as an integral part in accordance with 4.1.4;

p) degree of accuracy claimed for implants with a measuring function.

4.9 Clinical evaluation

If conformity with the fundamental principles for implants should be based on clinical data, such data should be established by either

a) a compilation of the relevant scientific literature currently available on the purpose intended by the manufacturer, or

b) the results of all the clinical investigations carried out in a way that protects the human subjects and ensures the scientific conduct of the investigation.

Annex A
(informative)

Correspondence to some regulatory documents

A.1 General

The following reference matrix in Table A.1 shows examples of the correspondence between the fundamental principles addressed in this Technical Report and a number of existing national/regional regulatory documents known as of 1 September 2003. Other countries not listed in the table may also have, or be developing, such regulations.

The comparative table is intended to demonstrate similarities which exist in the documents referenced. However, some of the items which are addressed in existing national/regional documents, which may, in particular, be of a quality or regulatory nature, may not be addressed in this Technical Report, by virtue of its scope.

The following clauses explain some of the terms and abbreviated terms used in the matrix.

A.2 European Economic Area

a) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; *Official Journal of the European Communities*, Vol. **36**, L 169, 12 July 1993 (referred to as “MDD” in the following).

b) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices; *Official Journal of the European Communities*, Vol. **33**, L 189, 20 July 1990 (referred to as “AIMDD” in the following).

A.3 Australia

Therapeutic Goods Regulations refers to *Therapeutic Goods (Medical Devices) Regulations*, 2002, Schedule 1.

A.4 Canada

“The Act” refers to the Canadian Food and Drugs Act.

“MDR” refers to the Canadian Medical Device Regulations. (SIII refers to schedule III of the Medical Device Regulations which deals with one type of active implant - the cardiac pacemaker.)

“SGMDR” refers to the Submission Guide for MDR Part V. (The numbers refer to Section 3 “General requirements” or to one of the appendices in the submission guide.)

“CAN/CSA” refers to CAN/CSA C22.2 No 601.1 - M90 (Prior to January 13, 1994, electromedical equipment was covered under Schedule VII of the Canadian Medical Devices Regulations. On January 13, 1994, Schedule VII was revoked by P.C. 1994-63. Such equipment is now totally regulated under the Canadian National Electric Code (C22.2), which is administered by the Provincial Governments. C22.2 No. 601.1 is essentially identical to IEC 60601-1 Second Edition.)

A.5 China

YY0340 refers to Implants for Surgery—Fundamental Principles, YY0340-2002, a professional standard for medicine, identical to ISO/TR 14283:1995, effective from 1 April 2003.

YY0341 refers to General Technological Requirements for Non-active Metallic Surgery Implants for Osteosynthesis YY0341-2002, a professional standard for medicine, the revised edition of a national standard GB 12417-90, effective from 1 April 2003.

Y30 refers to Provision for Administrations of Medical Devices Instructions for Use, effective from 1 May 2002.

A.6 Japan

"The Law" refers to the Pharmaceutical Affairs Law, Amended, published in June 2001.

Act 14	—	Approval for Manufacturing of Drugs, Medical Devices, and Others
Act 19-2	—	Approval for Manufacturing of Imported Drugs, Medical Devices, and Others
Act 63	—	Description Matters for Package of Medical Devices
Act 63-2	—	Description Matters for Instruction of Medical Devices
Act 64	—	Clear and Forbidden Expression for Instruction
Act 74-2	—	Annulment of Approval for Drugs, Medical Devices, and Others
Act 75-2	—	Annulment of Approval for Imported Drugs, Medical Devices, and Others
Act 77-5	—	Preparation and Keeping of Records for Special Medical Devices
Act 77-6	—	Guidance and Advice of Records for Manufacturer, Distributor, and Medical Staff

"GMP" refers to the Regulation of Manufacturing and Quality Control of Medical Devices.

"GCP" refers to the Standard for Clinical Investigation of Medical Devices.

From 3.1 to 3.6	—	The Law: Act 14, 19-2, 74-2, 75-2, 77-5, 77-6, GMP
From 4.1.1 to 4.7.8.4	—	The Law: Act 14, 19-2, 74-2, 75-2
From 4.8.1 to 4.8.6(n)	—	The Law: Act 14, 19-2, 74-2, 75-2, 63, 63-2, 64
4.9	—	The Law: Act 14, 19-2, 74-2, 75-2, GCP

Table A.1

ISO/TR 14283	European Economic Area		Australia	Canada	China	Japan
	MDD Annex I	AIMDD Annex 1	Therapeutic Goods Regulations		YY0340 YY0341, Y30	JAPAN MHLW Laws/GMP/GCP
3.1	1	1	1	The Act 19.	YY0340 3.1	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2 The Law: Act 77-5 The Law: Act 77-6 GMP
3.2	2	6	2		YY0340 3.2	
3.3	3	2	3	The Act 20. (1) The Act 21.	YY0340 3.3	
3.4	4	3	4	SGMDR 3.12 (a)	YY0340 3.4	
3.5	5	4	5	SGMDR 3.14 CAN/CSA 10.1	YY0340 3.5	
3.6	6	5	6	MDR 35. (1) (b) (iii)	YY0340 3.6	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2
4.1.1	7.1	9 (i), 9 (ii)	7.1		YY0340 4.1.1 YY0341 4.1~4.6	
4.1.1 a)	7.1	9 (i), 9 (ii)		MDR 35. (1) (a) (iv)	YY0340 4.1.1(a)	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2
4.1.1 b)	7.1	9 (i), 9 (ii)		MDR 35. (1) (a) (vii)	YY0340 4.1.1(b)	
4.1.2	7.2	—	7.2	MDR 35. (1) (a) (vii) SGMDR 3.10. (f), (g)	YY0340 4.1.2	
4.1.3	7.3	9 (iii)	7.3		YY0340 4.1.3	
4.1.4	7.4	10	7.4		YY0340 4.1.4	
4.1.5	7.5	9 (vi)	7.5	CAN/CSA 44.4	YY0340 4.1.5	
4.1.6	7.6	9 (vi)	7.6	CAN/CSA 44.6	YY0340 4.1.6	
4.1.7	—	9 (vii)	9.1		YY0340 4.1.7	
4.2.1	8.1	—	8.1	SGMDR 3.10. (3)	YY0340 4.2.1	
4.2.2	8.2	—	8.2 (1) (a)	SGMDR 3.8 (e)	YY0340 4.2.2	
4.2.3	8.3	7	8.3 (2)	SGMDR 3.10. (l) (j)	YY0340 4.2.3 YY0341 9.1.3	
4.2.4	8.4	—	8.3 (3)	MDR 35. (1) (a) (v) MDR 35. (1) (a) (vii) SGMDR 3.10. (1) (c)	YY0340 4.2.4	
4.2.5	8.5	—	8.3 (4)	MDR 35. (1) (a) (vi) SGMDR 3.7. (b)	YY0340 4.2.5	
4.2.6	8.6	—	8.4	SGMDR 3.10. (1) (j)	YY0340 4.2.6	
4.2.7	8.7	—	8.5	MDR SIII-6. (c)	YY0340 4.2.7	
4.3.1	9.1	9 (iv)	9.1	CAN/CSA 56.3	YY0340 4.3.1	
4.3.2	9.2	8 (i), 8 (iii), 8 (iv), 8 (vi)	9.2 (a) - (f)	CAN/CSA 23./60. CAN/CSA Section 5. CAN/CSA 19./59.	YY0340 4.3.2	
4.3.3	9.3	—	9.2 (g)	CAN/CSA Section 6.	YY0340 4.3.3	
4.4.1	10.1	—	10 (1)		YY0340 4.4.1	
4.4.1.1	10.2	—	10 (2)	CAN/CSA 6.	YY0340 4.4.1.1	
4.4.1.2	12.9	13	12.12 (4) & (5)	CAN/CSA 6. CAN/CSA 6.3	YY0340 4.4.1.2	

Table A.1 (*continued*)

ISO/TR 14283	European Economic Area		Australia	Canada	China	Japan
	MDD Annex I	AIMDD Annex 1	Therapeutic Goods Regulations		YY0340 YY0341, Y30	JAPAN MHLW Laws/GMP/GCP
4.4.2	10.3	—	10 (3)		YY0340 4.4.2	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2
4.5.1	11.1.1	—	11.1		YY0340 4.5.1	
4.5.2.1	11.2.1	—	11.2 (1) - (3)		YY0340 4.5.2.1	
4.5.2.2	11.2.2	—	11.2 (4)		YY0340 4.5.2.2	
4.5.3	11.3.1	8 (v)	11.3	CAN/CSA 29.2	YY0340 4.5.3	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2
4.5.4	11.4.1	—	11.4	MDR SIII-4. (h)	YY0340 4.5.4	
4.6.1	11.5.1	—	11.5 (2)	CAN/CSA[a]	YY0340 4.6.1	
4.6.2	11.5.2	—	11.5 (3)		YY0340 4.6.2	
4.6.3	11.5.3	—	11.5 (4)		YY0340 4.6.3	
4.7.1	12.1[b]	9 (vii)	12.1		YY0340 4.7.1	
4.7.2	12.2[b]	9 (v)	12.2	MDR SIII-6. (k)	YY0340 4.7.2	
4.7.3	—	12	12.13	MDR SIII-4. (f)	YY0340 4.7.3	
4.7.4	12.3[b]	9 (v)	12.3	CAN/CSA 49.2	YY0340 4.7.4	
4.7.5	12.4[b]	—	12.4		YY0340 4.7.5	
4.7.6.1	12.6[b]	—	12.5	CAN/CSA 19.	YY0340 4.7.6.1	
4.7.6.2	12.7.5[b]	8 (ii)	12.6	CAN/CSA 19. CAN/CSA 42. CAN/CSA 59.	YY0340 4.7.6.2	
4.7.7.1	12.7.1[b]	—	12.7	CAN/CSA Section 4.	YY0340 4.7.7.1	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2
4.7.7.2	12.7.2[b]	—	12.8		YY0340 4.7.7.2	
4.7.7.3	12.7.3[b]	—	12.9		YY0340 4.7.7.3	
4.7.7.4	12.7.4[b]	—	12.10	CAN/CSA 56.3	YY0340 4.7.7.4	
4.7.8.1	—	9 (vi)	—		YY0340 4.7.8.1	
4.7.8.2	12.8.1[b]	9 (vii)	12.12 (2) (a)		YY0340 4.7.8.2	
4.7.8.3	12.8.2[b]	——	12.12 (2) (b)		YY0340 4.7.8.3	
4.7.8.4	12.8.2[b]	—	12.12 (2) (b)		YY0340 4.7.8.4	
4.8.1	13.1	—	13.1	MDR 6.1. (e) MDR 6.1. (f) CAN/CSA 6.8	YY0340 4.8.1	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2 The Law: Act 63 The Law: Act 63-2 The Law: Act 64
4.8.2	13.2	14	13.1 (6)	CAN/CSA 6.4	YY0340 4.8.2	
4.8.3	13.3	14.1, 14.2	13.3		YY0340 4.8.3 YY0341 9.2.2(a)~(f)	
4.8.3 a)				MDR 6. (1) (b)	YY0340 4.8.3(a)	
4.8.3 b)				MDR 6. (1) (a)/ 6. (1) (d)/ 6. (1) (i)	YY0340 4.8.3(b)	
4.8.3 c)				MDR 6. (1) (g)	YY0340 4.8.3(c)	

Table A.1 (*continued*)

ISO/TR 14283	European Economic Area		Australia	Canada	China	Japan
	MDD Annex I	AIMDD Annex 1	Therapeutic Goods Regulations		YY0340 YY0341, Y30	JAPAN MHLW Laws/GMP/GCP
4.8.3 d)				MDR 6. (1) (c)	YY0340 4.8.3(d)	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2 The Law: Act 63 The Law: Act 63-2 The Law: Act 64
4.8.3 e)				MDR 6. (1) (h)	YY0340 4.8.3(e)	
4.8.3 g)				MDR N/A[c]	YY0340 4.8.3(g)	
4.8.3 h)				SGMDR 3.15 (d)[d]	YY0340 4.8.3(h)	
4.8.3 i)				MDR SIII-3. (a) CAN/CSA 6.8.3 (d)	YY0340 4.8.3(i)	
4.8.3 j)				MDR 6. (1) (f)	YY0340 4.8.3(j)	
4.8.3 k)				MDR 6. (1) (f)	YY0340 4.8.3(k)	
4.8.3 m)				MDR 35. (1) (a) (v)	YY0340 4.8.3(m)	
4.8.4	13.4	—	—	MDR 6.1. (e)	YY0340 4.8.4	
4.8.5	13.5	11	—	MDR SIII-2. (d)	YY0340 4.8.5	
4.8.6	13.6	15	13.4 (3)		YY0340 4.8.6 YY0341 7 Y30 Artcle 8, 13,14	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2 The Law: Act 63 The Law: Act 63-2 The Law: Act 64
4.8.6 a)				MDR SIII-4.	YY0340 4.8.6(a)	
4.8.6 b)				SGMDR 3.3 SGMDR 3.6 (a)	YY0340 4.8.6(b)	
4.8.6 c)				MDR SIII-4. (g)	YY0340 4.8.6(c)	
4.8.6 d)				MDR 3.4. (d) CAN/CSA 6.8.3(a)	YY0340 4.8.6(d)	
4.8.6 e)				SGMDR SIII-3.4 (c)	YY0340 4.8.6(e)	
4.8.6 f)				SGMDR Appendix I	YY0340 4.8.6(f)	
4.8.6 g)				MDR SIII-6 (e)	YY0340 4.8.6(g)	
4.8.6 h)				MDR 3.10. (2) CAN/CSA 6.8.2 (d) MDR SIII-6. (c)	YY0340 4.8.6(h)	
4.8.6 i)				SGMDR 3.6 (b)	YY0340 4.8.6(j)	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2 The Law: Act 63 The Law: Act 63-2 The Law: Act 64
4.8.6 k)				MDR SIII-6. (k)	YY0340 4.8.6(k)	
4.8.6 l)				MDR SIII-6 (t)	YY0340 4.8.6(l)	
4.8.6 n)				SGMDR 3.8. (h)	YY0340 4.8.6(n)	
4.9	14	16	14	MDR 35. (1) (b) (i) SGMDR Appendix VI	YY0340 4.9	The Law: Act 14 The Law: Act 19-2 The Law: Act 74-2 The Law: Act 75-2 GCP

[a] CAN/CSA C22.2 No. 601.1 contains provisions for protections against hazards from unwanted or excessive radiation, including particle, microwave, light (laser, infra-red, ultraviolet), and acoustical energy. However, all of these sections are marked as under consideration.

[b] Sections addressing active medical devices that include concepts similar to the Fundamental Principles.

[c] A practitioner on compassionate grounds may obtain from the Canadian Government permission to purchase, for the making of diagnoses in respect of or the provisions of care to the practitioner's patients, devices which would not otherwise be available in Canada.

[d] In Canada, the specific wording required on the label is “For Clinical Trial Use Only”.

Bibliography

The following International Standards may be used to link these fundamental principles to the respective standards giving product-related requirements for implants:

[1] ISO 31 (all parts), *Quantities and units*

[2] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[3] ISO 14630, *Non-active surgical implants — General requirements*

[4] ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

Guidance on the analysis of risks associated with the use of implants can be found in the following document:

[5] ISO 14971, *Medical devices — Application of risk management to medical devices*

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