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Non-active surgical implants - Implants for osteosynthesis - Particular requirements (ISO 14602:2010)

Implants chirurgicaux non actifs - Implants pour ostéosynthèse - Exigences particulières (ISO 14602:2010)

Nichtaktive chirurgische Implantate - Implantate zur Osteosynthese - Besondere Anforderungen (ISO 14602:2010)

This European Standard was approved by CEN on 20 September 2011.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 14602:2011) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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

This document supersedes EN ISO 14602:2010.

This new edition contains a revised Annex ZA.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14602:2010 has been approved by CEN as EN ISO 14602:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices as amended by Directive 2007/47/EC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between Directive 93/42/EEC and this European Standard

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5, 7, 8 and 10	7.2	
6	7.3	
5	7.5 1st sentence	
5 and 6	7.6	
10	8.3	
9	8.4	
9	8.5	
10	8.6	
11.2	8.7	
11.4	9.1	
5 and 6	9.2 2nd indent	
11.1	13.2	
11.2	13.3 a) 1st sentence	
11.2	13.3 b)	
11.2	13.3 c)	
11.2	13.3 d)	
11.2	13.3 e)	
11.2	13.3 f)	
11.6	13.3 g)	
11.6	13.3 h)	
10 and 11.2	13.3 i)	
11.2	13.3 j)	

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
11.2	13.3 k)	
11.2	13.3 m)	
11.2 and 11.3	13.4	
4.3	13.5	
11.3	13.6 a)	
11.3 and 11.4	13.6 c)	
11.3	13.6 e)	
9	13.6 g)	
9	13.6 i)	
11.3 b)	13.6 k)	
11.3	13.6 n)	
11.3 b)	13.6 q)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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 14602 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

This second edition cancels and replaces the first edition (ISO 14602:1998), which has been technically revised.

Introduction

In general, non-active surgical implants for osteosynthesis are used in trauma treatment or corrective surgery. They maintain the reduction of fractured bones and stabilize bony (or adjacent) structures to allow bone healing or fusion and/or to provide support or correction. When they have achieved their objective, the implants are either retrieved or left *in situ*.

This International Standard, in addition to the requirements in ISO 14630, provides a method for addressing the fundamental principles in ISO/TR 14283 as they apply to non-active surgical implants for osteosynthesis. Annex A shows the correspondence between the clauses of this International Standard and those of ISO/TR 14283:2004.

This International Standard also provides a method of demonstrating compliance with the relevant essential requirements (ERs) as outlined in general terms in Annex 1 of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive 2007/47/EC of 5 September 2007, as they apply to non-active surgical implants for osteosynthesis. It might also assist manufacturers to comply with the requirements of other regulatory bodies.

Alternative methods of demonstrating compliance might be acceptable, in particular with respect to implants which have demonstrated satisfactory long-term clinical performance.

There are three levels of standard concerned with non-active surgical implants and related instrumentation. For the implants themselves, there are the following levels, 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 contain requirements that apply to all non-active surgical implants. They also indicate that additional requirements are given in the level 2 and level 3 standards.

Level 2 standards, such as this International Standard, contain requirements that apply to a more restricted set or family of non-active surgical implants. This International Standard is a Level 2 standard that lays down particular requirements for non-active surgical implants for osteosynthesis that are in addition to those general requirements stated in ISO 14630 for non-active surgical implants. It is to be applied in conjunction with ISO 14630.

Level 3 standards, such as those listed in the annexes, apply to specific types of implant within a family of non-active surgical implants, in this case particular types of non-active surgical implant for osteosynthesis.

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.

Non-active surgical implants — Implants for osteosynthesis — Particular requirements

1 Scope

This International Standard specifies particular requirements for non-active surgical implants for osteosynthesis, hereafter referred to as implants.

In addition to ISO 14630, this International Standard gives particular requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14630:2008, *Non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630 and the following apply.

3.1
non-active surgical implant for osteosynthesis
non-active implantable device intended to provide support to bony, cartilaginous, tendinous or ligamentous structures

4 Intended performance

4.1 General

The intended performance of implants shall conform to ISO 14630:2008, Clause 4, taking account of the additional aspects listed in 4.2, 4.3 and 4.4 as applicable.

NOTE Because of variations in anatomy, fracture sites and applications, it is necessary that implants for osteosynthesis be versatile. For anatomical reasons the size of the implants is necessarily restricted. The condition of the bone and the configuration of bony and other defects can affect the performance of the implants.

4.2 Intended purpose

The intended purpose is osteosynthesis, which can include the areas of application listed below. In describing and documenting the implant's intended performance for osteosynthesis, the area(s) of intended typical application(s) shall be specified, for example:

a) fracture treatment;

b) tumour treatment;

c) stabilization of osteotomy;

d) stabilization of arthrodesis;

e) bone lengthening, shortening or transport;

f) support of bone replacement (bone graft sites);

g) adjunct to joint replacement;

h) scoliosis treatment;

i) spinal stabilization;

j) treatment of degenerative diseases;

k) tendon reconstruction;

l) ligament reconstruction.

NOTE Where appropriate, the anatomical site(s) should be indicated.

4.3 Functional characteristics

In describing and documenting the functional characteristics of the implants, the following aspects shall be addressed as appropriate:

a) type of fixation to bony, cartilaginous, tendinous or ligamentous structures;

b) means of attachment to or anchorage in bone;

c) linkage between implant components and bone or other structures;

d) use for revision procedures;

e) ability to be removed;

f) action on bone and adjacent structures, for example:

- stabilization;
- support of the reduction of fractures and dislocations of bone and other structures;
- correction or control of alignment;
- transport of fragments;
- control of compression or distraction;
- safe placement in relation to adjacent structures.

4.4 Intended conditions of use

Variables that can influence the intended performance of the implant, including the following, shall be taken into account:

a) body build (size, weight);

b) age of patient;

c) pathological conditions;

d) bone quality;

e) tissue vitality;

f) surrounding tissue conditions;

g) loading conditions;

h) method of implantation;

i) interaction and combination with other fixation device;

j) activity level of the patient;

NOTE Certain conditions might restrict the application of the implants or call for caution in clinical usage. The performance of the implant might be affected by patient-related conditions.

k) operative techniques;

l) methods of post-operative treatment.

5 Design attributes

The requirements of Clause 5 of ISO 14630:2008 apply, together with the following particular requirements.

a) Where implants are designed as part of an interconnecting system, shape, dimensions and tolerances shall be such that the intended use and performance of the implant is not impaired.

NOTE 1 Where an implant comprises two or more components, the design should be such that potential wear as well as electrolytic and corrosive effects are taken into account [compare with items 5 a), c), h), k) and l) of ISO 14630:2008].

b) Where appropriate, the dimensions of the implants shall be consistent with the anatomical features of the population for whom they are intended.

NOTE 2 The design of the implants should take into account anatomical structures, types of tissue defect and bone healing/fusion rates. The final design can be a compromise that satisfies such diverse requirements.

c) The designer of the implant shall consider the required operative techniques and the appropriate care and handling of the implant to reduce the risk of use error while not impairing the intended use and performance of the implant.

NOTE 3 Annex B contains an informative list of standard implant designs found acceptable through proven use for given applications.

6 Materials

The requirements of Clause 6 of ISO 14630:2008 apply.

NOTE In Annex C, an informative list of standards is provided for materials found acceptable for different types of implant through proven clinical use.

7 Design evaluation

7.1 General

Implants shall be evaluated in accordance with ISO 14630:2008, Clause 7, together with the following particular requirements for preclinical evaluation.

NOTE Annex D provides a list of standards that can be used to assess compliance with requirements stated above for different types of implant.

7.2 Pre-clinical evaluation

The requirements of 7.2 of ISO 14630:2008 apply, together with the following particular requirements.

a) *In vitro* handling tests shall be carried out to verify the intended interaction between the implant and the instrumentation and, if appropriate, between interconnecting implants.

   In instances when implantation and, where appropriate, removal cannot be evaluated by direct comparison with existing devices, cadaveric evaluation should be performed where possible.

b) If static and/or dynamic loading tests are relevant for the evaluation of the implant, either accepted test standards, when available, or customized test models taking into account the characteristics of the implant shall be applied. Because of the wide variance of implants and their features, testing standards might not exist or may be modified as needed.

c) When properly validated, biophysical or modelling research may be used to demonstrate that the intended performance of the implant is achieved.

NOTE 1 The extent of preclinical evaluation takes account of existing data in relation to similar implants or design features.

NOTE 2 Test methods can be related to different levels of testing: a) basic technical testing of implants or implant sections for characterization of the device (e.g. tensile, bending, torsion); b) testing of mounted components in relation to anticipated loading conditions; c) testing of assemblies of parts under biomechanical conditions (bone can be replaced by suitable artificial material); d) testing under static conditions or dynamic conditions (cyclic fatigue).

NOTE 3 Tests can be set up to evaluate features of specific implants or assemblies in relation to specific loading conditions and/or environmental conditions.

7.3 Clinical evaluation

The requirements of 7.3 of ISO 14630:2008 apply.

7.4 Post-market surveillance

The requirements of 7.4 of ISO 14630:2008 apply.

8 Manufacturing

The requirements of Clause 8 of ISO 14630:2008 apply.

9 Sterilization

The requirements of Clause 9 of ISO 14630:2008 apply.

10 Packaging

The requirements of Clause 10 of ISO 14630:2008 apply.

11 Information supplied by manufacturer

11.1 General

The requirements of 11.1 of ISO 14630:2008 apply.

11.2 Labelling

The requirements of 11.2 of ISO 14630:2008 apply.

11.3 Instructions for use

The requirements of 11.3 of ISO 14630:2008 apply, together with the following particular requirements. The information supplied by the manufacturer shall include the following details when relevant:

a) any constraints concerning modifications to the implant after supply, e.g. size, shape, surface condition;

b) the date of issue or the latest revision of the instructions for use.

11.4 Restrictions on combinations

The requirements of 11.4 of ISO 14630:2008 apply.

11.5 Marking on implant

The requirements of 11.5 of ISO 14630:2008, apply together with the following particular requirement.

The marking on an implant shall be made and placed in such a way that it does not affect its intended performance.

11.6 Marking for special purposes

The requirements of 11.6 of ISO 14630:2008 apply.

Annex A
(informative)

Correspondence of the clauses of this International Standard to the fundamental principles outlined in ISO/TR 14283

Table A.1 — Correspondence between this International Standard and ISO/TR 14283

Clause of this International Standard	Relates to subclause of ISO/TR 14283:2004
4	3.1 – 3.2 – 3.4 – 4.1.1
5	3.1 – 3.2 – 3.3 – 3.4 – 3.5 – 4.1.1 – 4.1.2 – 4.1.3 – 4.1.5 – 4.1.6 – 4.2 – 4.3.1 – 4.3.2
6	3.1 – 3.2 – 4.1.1 – 4.1.2 – 4.1.3 – 4.1.4 – 4.1.5 – 4.2.2 – 4.3.2
7	3.1 – 3.2 – 3.3 – 3.4 – 3.6 – 4.1.1 – 4.1.2 – 4.1.3 – 4.1.5 – 4.1.6 – 4.2 – 4.3.1 – 4.3.2 – 4.9
8	3.1 – 3.2 – 3.3 – 3.5 – 4.1.1 – 4.1.2
9	3.1 – 3.2 – 4.1.2 – 4.2.1 – 4.2.3 – 4.2.4
10	3.1 – 3.2 – 3.3 – 3.5 – 4.1.2 – 4.2.4
11	3.1 – 3.2 – 4.2.7 – 4.8.1

Annex B
(informative)

ISO standards referring to implants and associated instruments found acceptable through clinical use for given applications in osteosynthesis

NOTE A listing of informative standards, including other parts of this series of International Standards, can be found in the Bibliography of ISO 14630:2008.

B.1 Overview of different types of implants and associated instruments for osteosynthesis

The related International Standards are listed under the numbers added in parentheses.

a) General requirement covering osteosynthesis implants and instruments (see B.2):

b) Osteosynthesis implants (see B.3):

- bone screws (see B.3.1);
- bone plates (see B.3.2);
- intramedullary fixation devices (see B.3.3);
- implants for fixation of the ends of the femur (see B.3.4);
- skeletal pins and wires (see B.3.5);
- staples (see B.3.6);
- malleable wires for cerclages and other fixation purposes (see B.3.7);
- devices for external fixation of bones (see B.3.8).

c) Associated instruments (see B.4):

- drive connection instruments (see B.4.1);
- drilling and tapping instruments (see B.4.2).

B.2 General requirements and guidance

- ISO 8828, *Implants for surgery — Guidance on care and handling of orthopaedic implants*
- ISO/TR 9586, *Implants for surgery — Usage of the terms “valgus” and “varus” in orthopaedic surgery*
- ISO 15374, *Implants for surgery — Requirements for production of forgings*

B.3 Types of osteosynthesis implants and related ISO standards

B.3.1 Bone screws

— ISO 5835, *Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions*

— ISO 9268, *Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions*

B.3.2 Bone plates

— ISO 5836, *Implants for surgery — Metal bone plates — Holes corresponding to screws with asymmetrical threads and spherical under-surface*

— ISO 9269, *Implants for surgery — Metal bone plates — Holes and slots corresponding to screws with conical under-surface*

B.3.3 Intramedullary fixation devices

— ISO 5837-1, *Implants for surgery — Intramedullary nailing systems — Part 1: Intramedullary nails, with cloverleaf or V-shaped cross-section*

— ISO 5837-2, *Implants for surgery — Intramedullary nailing systems — Part 2: Medullary pins*

— ISO 15142-1, *Implants for surgery — Metal intramedullary nailing systems — Part 1: Intramedullary nails*

— ISO 15142-2, *Implants for surgery — Metal intramedullary nailing systems — Part 2: Locking components*

— ISO 15142-3, *Implants for surgery — Metal intramedullary nailing systems — Part 3: Connection devices and reamer diameter measurements*

B.3.4 Implants for fixation of the ends of the femur

— ISO 8615, *Implants for surgery — Fixation devices for use in the ends of the femur in adults*

B.3.5 Skeletal pins and wires

— ISO 5838-1, *Implants for surgery — Skeletal pins and wires — Part 1: Material and mechanical requirements*

— ISO 5838-2, *Implants for surgery — Skeletal pins and wires — Part 2: Steinmann skeletal pins — Dimensions*

— ISO 5838-3, *Implants for surgery — Skeletal pins and wires — Part 3: Kirschner skeletal wires*

B.3.6 Staples

— ISO 8827, *Implants for surgery — Staples with parallel legs for orthopaedic use — General requirements*

B.3.7 Malleable wires for cerclages and other fixation purposes

— ISO 10334, *Implants for surgery — Malleable wires for use as sutures and other surgical applications*

B.3.8 Devices for external fixation of bones

NOTE There are no International Standards on this subject as yet.

B.3.9 Devices for fixation of the spine

NOTE There are no International Standards on this subject as yet.

B.4 ISO standards related to associated instruments

B.4.1 Drive connection instruments

— ISO 8319-1, *Orthopaedic instruments — Drive connections — Part 1: Keys for use with screws with hexagon socket heads*

— ISO 8319-2, *Orthopaedic instruments — Drive connections — Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws*

B.4.2 Drilling and tapping instruments

— ISO 9714-1, *Orthopaedic drilling instruments — Part 1: Drill bits, taps and countersink cutters*

Annex C
(informative)

ISO Standards referring to materials found acceptable through proven clinical use

— ISO 5832-1, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*

— ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

— ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

— ISO 5832-4, *Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy*

— ISO 5832-5, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*

— ISO 5832-6, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*

— ISO 5832-7, *Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*

— ISO 5832-8, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*

— ISO 5832-9, *Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel*

— ISO 5832-11, *Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

— ISO 5832-12, *Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy*

— ISO 5832-14, *Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy*

— ISO 5833, *Implants for surgery — Acrylic resin cements*

— ISO 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

— ISO 5834-2, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms*

— ISO 6474-1, *Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina*

— ISO 6474-2[1)], *Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high purity alumina matrix with zirconia reinforcement*

1) To be published.

— ISO 13356, *Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*

— ISO 13779-1, *Implants for surgery — Hydroxyapatite — Part 1: Ceramic hydroxyapatite*

— ISO 13779-2, *Implants for surgery — Hydroxyapatite — Part 2: Coatings of hydroxyapatite*

— ISO 13782, *Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications*

— ISO 14949, *Implants for surgery — Two-part addition-cure silicone elastomers*

— ISO 20160, *Implants for surgery — Metallic materials — Classification of microstructures for alpha+beta titanium alloy bars*

NOTE Certain similar national standards might be equally applicable.

Annex D
(informative)

Standards related to testing and design evaluation

— ISO 5834-3, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 3: Accelerated ageing methods*

— ISO 5834-4, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 4: Oxidation index measurement method*

— ISO 5834-5, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 5: Morphology assessment method*

— ISO 6475, *Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods*

— ISO 9583, *Implants for surgery — Non-destructive testing — Liquid penetrant inspection of metallic surgical implants*

— ISO 9584, *Implants for surgery — Non-destructive testing — Radiographic examination of cast metallic surgical implants*

— ISO 9585, *Implants for surgery — Determination of bending strength and stiffness of bone plates*

— ISO 13779-3, *Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity and phase purity*

— ISO 13779-4, *Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength*

— ISO 15814, *Implants for surgery — Copolymers and blends based on polylactide — In Vitro degradation testing*

— ISO 16402, *Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopaedics*

— ISO 16428, *Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices*

— ISO 16429, *Implants for surgery — Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods*

— ISO 20160, *Implants for surgery — Metallic materials — Classification of microstructures for alpha+beta titanium alloy bars*

— ISO 23317, *Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials*

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[1] ISO/TR 14283:2004, *Implants for surgery — Fundamental principles*