DRAFT AMENDMENT ISO 14630:2008/DAM 1

ISO/TC **150** Secretariat: **DIN**

Voting begins on **2011-01-20** Voting terminates on **2011-06-20**

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

Non-active surgical implants — General requirements

AMENDMENT 1

Implants chirurgicaux non actifs — Exigences générales

AMENDEMENT 1

ICS 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

Amendment 1 to ISO 14630:2008 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, and by Technical Committee CEN/TC 285, *Non-active surgical implants* in collaboration.

Introduction

This amendment is intended to address certain new fundamental principles that have been identified as a result of the amendment of the European Medical Device Directive as they apply to non-active surgical implants. This amendment was requested by CEN/TC 285.

Non-active surgical implants — General requirements

AMENDMENT 1

5 Design attributes

Insert after item i)

NOTE The shape, dimensions and tolerances of the interconnections should be taken into account. Also, potential wear, degradation, corrosion and electrolytic effects should be taken into account.

Insert following item r):

s) where appropriate, the anatomical features of the population for whom the implant is intended;

t) the condition and pathology of the host tissue;

u) 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.

7 Design evaluation

7.2 Pre-clinical evaluation

Replace Subclause 7.2 with:

Implants shall undergo pre-clinical evaluation based on,

a) the relevant scientific literature relating to the safety, performance, the design characteristics, and the intended use of the implant

b) analysis of available predictive and outcome data from sources such as national and other registries, and

c) analysis of data obtained from testing including bench-testing and, when available, data from validated techniques for evaluating implant safety and intended performance.

The extent of preclinical evaluation shall take account of existing data in relation to similar implants or design features.

Pre-clinical testing of implants shall simulate conditions of intended use. Test methods and related limits for specific types of implants shall be defined and justified by the manufacturer, and shall include, as appropriate, in vitro handling tests to verify the intended interaction between the implant and the instrumentation, and if applicable, 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.

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.

Where appropriate, biophysical or modelling research may be used to demonstrate that the intended performance of the implant is achieved.

NOTE 1 Test methods can be related to different levels of testing such as:

— basic technical testing of implants or implant sections for characterization of the device. (e.g. tensile, bending, torsion);

— testing of mounted components in relation to anticipated loading conditions;

— testing of assemblies of parts;

— biomechanical conditions (tissue can be replaced by suitable artificial material); and

— testing under static conditions or dynamic conditions (cyclic fatigue).

NOTE 2 Tests can be set up for evaluation of features of specific implants or assemblies in relation to specific loading conditions and/or environmental conditions.

NOTE 3 Test methods and limits for particular implants can be described in other related International Standards, such as those listed in the bibliography.

11 Information supplied by manufacturer

11.3 Instructions for use

Insert following the sixth bullet of item t):

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

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC as amended by EU Directive 2007/47/EC

NOTE This annex, which is required for adoption as a European Standard under the mandate give to CEN by the European Commission and the European Free Trade Association, will be removed from the ISO published edition.

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 Communities 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 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 — Correspondence between this European Standard and Directive 93/42/EEC as amended by Directive 2007/47/EC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC as amended by Directive 2007/47/EC	Qualifying remarks/Notes
4	1 – 2 – 3 – 4 – 5 – 7.1	
5	1 – 2 – 3 – 4 – 5 – 7.1 – 7.2 – 7.3 – 7.5 – 7.6 – 8 – 9.1 – 9.2	
6	1 – 2 – 7.1 – 7.2 – 7.3 – 7.4 – 7.5 – 8.2 – 9.2	
7	1 – 2 – 3 – 4 – 6 – 6.a – 7.1 – 7.2 – 7.3 – 7.5 – 7.6 – 8 – 9.1 – 9.2	
8	1 – 2 – 3 – 5 – 7.1 – 7.2	
9	1 – 2 – 7.2 – 8.1 – 8.3 – 8.4 – 8.5	
10	1 – 2 – 3 – 5 – 7.2 – 8.3 – 8.6	
11	1 – 2 – 8.7 – 13	The part of ER 13.3 a) concerning the information on the manufacturer's authorized representative in the European Community is not addressed in this European Standard ER: 13.3 f) is only partially addressed in this European Standard. The safety issue is addressed, but not the regulatory requirement that the manufacturer's indication of single use must be consistent across the European community. ER: 13.6 h) is only partially

		addressed in this European Standard, since in case the device bears an indication that it is for single use, the information on characteristics and technical factors known to the manufacturer that could pose a risk if the device were re-used is not included.

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