MITTEAKTIIVSED KIRURGILISED IMPLANTAADID. RINNAIMPLANTAADID. ERINÕUDED

Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2018, Corrected version 2018-08)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 14607:2018 sisaldab Euroopa standardi EN ISO 14607:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14607:2018 consists of the English text of the European standard EN ISO 14607:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.05.2018.	Date of Availability of the European standard is 16.05.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Nichtaktive chirurgische Implantate - Mammaimplantate - Besondere Anforderungen (ISO 14607:2018)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 14607:2018) 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of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

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

This document supersedes EN ISO 14607:2009.

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(s).

For relationship with EU Directive(s), 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 34-1:2015	–	ISO 34-1:2015
ISO 37:2017	–	ISO 37:2017
ISO 4287	EN ISO 4287:1998, EN ISO 4287:1998/AC:2008 and EN ISO 4287:1998/A1:2009	ISO 4287:1997, ISO 4287:1997/Cor 1:1998/Cor 2:2005 and ISO 4287:1997/Amd:2009

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 7619-1	–	ISO 7619-1:2010
ISO 10993-1	EN ISO 10993-1:2009 and EN ISO 10993-1:2009/AC:2010	ISO 10993-1:2009 and ISO 10993-1:2009/Cor 1:2010
ISO 10993-5	EN ISO 10993-5:2009	ISO 10993-5:2009
ISO 10993-18	EN ISO 10993-18:2009	ISO 10993-18:2005
ISO 11607-1	EN ISO 11607-1:2017	ISO 11607-1:2006 and ISO 11607-1:2006/Amd 1:2014
ISO 14155	EN ISO 14155:2011 and EN ISO 14155:2011/AC:2011	ISO 14155:2011 and ISO 14155:2011/Cor. 1:2011
ISO 14630:2012	EN ISO 14630:2012	ISO 14630:2012

Endorsement notice

The text of ISO 14607:2018, Corrected version 2018-08 has been approved by CEN as EN ISO 14607:2018 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
7.5	6.2, 6.3, 6.4, 7.2.2.1	The Essential Requirement is covered with respect to the risk posed by silicone gel leaking from the implant. The standard requires several tests to establish safe composition and properties of silicone gel. Beyond that the standard also requires several tests to establish the integrity of the implant shell to prevent leaks. Additionally, an evaluation of diffusion of gel through the implant shell is required in 7.3.4. Standard Clause 6.2 covers Directive Annex I, ER 7.5 in respect of cytotoxicity only. Standard Clause 6.3 covers Directive

Essential Requirements of directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
		Annex I, ER 7.5 in respect of oligomers, cyclotetrasiloxane (D4) and cyclopentasiloxane (D5) only. Standard Clause 6.4 covers Directive Annex I, ER 7.5 in respect of the specified metals and in production raw materials only. Standard Clause 7.2.2.1 covers Directive Annex I, ER 7.5 in respect of the integrity of the implant shell only.
9.2, second indent	7.2.2.2.2	The Essential Requirement is covered with respect to a potential external impact on the implant, e.g. due to the safety belt being triggered in a car accident. The standard provides an impact resistance test to make sure implants withstand such impacts. Standard Clause 7.2.2.2.2. covers Directive Annex I, ER 9.2 second dash in respect of impact resistance of the device only.
13.1	11.3, Annex I, Annex J	While the references to ISO 14630:2012 in 11.3 point to useful information, they are not considered relevant within the context of this Annex ZA. Only the requirements provided specifically in this standard should be considered when claiming coverage of the Essential Requirement with this standard.
13.3 a)	11.7.2 a), c), Annex J a)	Directive Annex I, ER 13.3 a) is covered in respect of name or trade name and address of the manufacturer only. The requirement regarding the name and address of authorized representative is not covered.

Essential Requirements of directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
13.3 b)	11.2	While the references to ISO 14630:2012 in 11.2 point to useful information, they are not considered relevant within the context of this Annex ZA. Only the requirements provided specifically in this standard, which only partly cover the Essential Requirement 13.3 b), should be considered when claiming coverage of the Essential Requirement with this standard.
13.3 d)	11.7.2 b)	—
13.3 j)	11.5, Annex I	Standard Clause 11.5 covers Directive Annex I, ER 13.3 i) in respect of filling materials only. Standard Annex I covers Directive Annex I, ER 13.3 i) only in respect of the aspects detailed in the standard.
13.3 k)	Annex I	The ER is covered only in respect of the aspects detailed in the standard.
13.6.d)	Annex I h)	Standard Annex I h) covers Directive Annex I, 13.6 d) provided the information is in the instructions for use.
13.6 e)	11.6, Annex J c), d), h)	Standard Clause 11.6 and Annex J c) and d) cover Directive Annex I, ER 13.6 e) only in respect of expected lifetime. Standard Annex J h) covers Directive Annex I, ER 13.6 e) only in respect of possible effects on breast feeding.
13.6. f)	11.3.3, Annex J j), k), l),	The ER is covered only in respect of the aspects detailed in the standard.
13.6 l)	Annex J l)	Standard Annex J l) covers Directive Annex I, 13.6 l) provided the information is in the instructions for use and is given to the patient.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products 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.

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.

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

This third edition cancels and replaces the second edition (ISO 14607:2007), which has been technically revised.

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

— limit values for trace elements have been added (6.4);

— determination of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in silicone gels (new Annex A) has been included;

— mechanical test on a mammary implant in its implantable state (new Annex C, previously Annex E), specifically the fatigue test (C.1), has undergone major revision;

— test for silicone gel penetration (silicone filling materials only) (new Annex F) has been included;

— silicone diffusion assessment from mammary implants by an *in vitro* method (new Annex G, previously Annex H) has undergone major revision;

— test for surface characteristics (new Annex H, previously Annex A) has undergone major revision.