Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy (ISO 5832-7:2016)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5832-7:2019 sisaldab Euroopa standardi EN ISO 5832-7:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5832-7:2019 consists of the English text of the European standard EN ISO 5832-7:2019.
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 02.10.2019.	Date of Availability of the European standard is 02.10.2019.
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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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5832-7

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English Version

Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy (ISO 5832-7:2016)

Implants chirurgicaux - Produits à base de métaux - Partie 7: Alliage à forger mis en forme à froid à base de cobalt, de chrome, de nickel, de molybdène et de fer (ISO 5832-7:2016)

Chirurgische Implantate - Metallische Werkstoffe - Teil 7: Schmiedbare und kaltumformbare Cobalt-Chrom-Nickel-Molybdän-Eisenlegierung (ISO 5832-7:2016)

This European Standard was approved by CEN on 2 September 2019.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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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

Ref. No. EN ISO 5832-7:2019 E

European foreword

The text of ISO 5832-7:2016 has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5832-7:2019 by 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 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

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.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5832-7:2016 has been approved by CEN as EN ISO 5832-7:2019 without any modification.

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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).

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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 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.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 5832-7:1994), which has been technically revised.

A list of all parts in the ISO 5832 series can be found on the ISO website.

Introduction

No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of the use of the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate conditions.

Implants for surgery — Metallic materials —

Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

1 Scope

This document specifies the characteristics of, and corresponding test methods for, forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy for use in the manufacture of surgical implants.

NOTE The mechanical properties of a sample obtained from a finished product made of this alloy do not necessarily comply with those specified in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 643, *Steels — Micrographic determination of the apparent grain size*

ISO 4967, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

3 Terms and definitions

No terms and definitions are listed in this document.

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

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

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

4 Chemical composition

The heat analysis of the alloy when determined as specified in Clause 7 shall comply with the chemical composition specified in Table 1. The analysis of samples taken from products manufactured from the alloy shall also comply with Table 1.