ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Február 2020

STN	**Implantáty pre chirurgiu Kovové materiály Časť 7: Kovateľná a za studena tvarovaná zliatina kobaltu, chrómu, niklu, molybdénu a železa (ISO 5832-7: 2016)**	**STN EN ISO 5832-7** 85 6364

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/20

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EUROPEAN STANDARD

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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.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.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO 5832-7

Third edition
2016-11-15

Implants for surgery — Metallic materials —

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

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

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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.

INTERNATIONAL STANDARD **ISO 5832-7:2016(E)**

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*

