STN	Chirurgické implantáty. Kovové materiály. Časť 3: Tvárnená zliatina titánu, 6-hliníka, 4-vanádia (ISO 5832-3: 2016).	STN EN ISO 5832-3
		85 6364

Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2016)

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. 04/17

Obsahuje: EN ISO 5832-3:2016, ISO 5832-3:2016

Oznámením tejto normy sa ruší STN EN ISO 5832-3 (85 6364) zo septembra 2012

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Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017

Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

#### STN EN ISO 5832-3: 2017

## EUROPEAN STANDARD NORME EUROPÉENNE

## EN ISO 5832-3

EUROPÄISCHE NORM

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**English Version** 

#### Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2016)

Implants chirurgicaux - Produits à base de métaux -Partie 3: Alliage corroyé à base de titane, d'aluminium-6 et de vanadium-4 (ISO 5832-3:2016) Chirurgische Implantate - Metallische Werkstoffe - Teil 3: Titan 6-Aluminium 4-Vanadium Knetlegierung (ISO 5832-3:2016)

This European Standard was approved by CEN on 12 September 2016.

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels** 

Ref. No. EN ISO 5832-3:2016 E

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#### **European foreword**

This document (EN ISO 5832-3:2016) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 55 "Dentistry" 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of an identical text or by endorsement, at the latest by May 2017, and conflicting national standards shall be withdrawn at the latest by May 2017.

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 5832-3:2012.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

#### **Endorsement notice**

The text of ISO 5832-3:2016 has been approved by CEN as EN ISO 5832-3:2016 without any modification.

## STN EN ISO 5832-3: 2017 INTERNATIONAL STANDARD



Fourth edition 2016-10-15

# Implants for surgery — Metallic materials —

## Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

Implants chirurgicaux — Produits à base de métaux — Partie 3: Alliage corroyé à base de titane, d'aluminium-6 et de vanadium-4



Reference number ISO 5832-3:2016(E)



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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 <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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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: <u>www.iso.org/iso/foreword.html</u>.

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

This fourth edition cancels and replaces the third edition (ISO 5832-3:1996), which has been technically revised.

ISO 5832 consists of the following parts, under the general title *Implants for surgery* — *Metallic materials:* 

- Part 1: Wrought stainless steel
- Part 2: Unalloyed titanium
- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
- Part 4: Cobalt-chromium-molybdenum casting alloy
- *Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*
- Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
- Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy
- Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy
- Part 9: Wrought high nitrogen stainless steel
- Part 11: Wrought titanium 6-aluminium 7-niobium alloy
- Part 12: Wrought cobalt-chromium-molybdenum alloy
- Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy

#### Introduction

No known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body. However, long-term clinical experience of the use of the material referred to in this part of ISO 5832 has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications.

STN EN ISO 5832-3: 2017

## Implants for surgery — Metallic materials —

## Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

#### 1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 4-vanadium alloy (Ti 6-AI4-V 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 may not necessarily comply with the specifications given in this part of ISO 5832.

#### 2 Normative references

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. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 6892-1<sup>1</sup>), Metallic materials — Tensile testing — Part 1: Method of test at room temperature

ISO 7438, Metallic materials — Bend test

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

EN 3114-003, Aerospace series — Test method — Microstructure of  $(\alpha+\beta)$  titanium alloy wrought products — Part 003: Microstructure of plate

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

<sup>1)</sup> To be published. (Revision of ISO 6892-1:2009)