# SLOVENSKI STANDARD
# SIST EN ISO 5832-3:2022

**01-februar-2022**

**Nadomešča:**
**SIST EN ISO 5832-3:2017**

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**Vsadki (implantati) za kirurgijo - Kovinski materiali - 3. del: Titanova 6-aluminijeva 4-vanadijeva zlitina (ISO 5832-3:2021)**

Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)



Chirurgische Implantate - Metallische Werkstoffe - Teil 3: Titan 6-Aluminium 4-Vanadium Knetlegierung (ISO 5832-3:2021)

Implants chirurgicaux - Matériaux métalliques - Partie 3: Alliage corroyé à base de titane, d'aluminium-6 et de vanadium-4 (ISO 5832-3:2021)



**Ta slovenski standard je istoveten z:** **EN ISO 5832-3:2021**

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**ICS:**

| | | |
|---|---|---|
| 11.040.40 | Implantanti za kirurgijo, protetiko in ortetiko | Implants for surgery, prosthetics and orthotics |

**SIST EN ISO 5832-3:2022** **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 5832-3

December 2021

ICS 11.040.40

Supersedes EN ISO 5832-3:2016

English Version

# Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)

Implants chirurgicaux - Matériaux métalliques - Partie 3: Alliage corroyé à base de titane, d'aluminium-6 et de vanadium-4 (ISO 5832-3:2021)

Chirurgische Implantate - Metallische Werkstoffe - Teil 3: Titan 6-Aluminium 4-Vanadium Knetlegierung (ISO 5832-3:2021)

This European Standard was approved by CEN on 30 October 2021.

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



Ref. No. EN ISO 5832-3:2021 E

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## European foreword

This document (EN ISO 5832-3:2021) 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 June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

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 5832-3:2016.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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 5832-3:2021 has been approved by CEN as EN ISO 5832-3:2021 without any modification.

INTERNATIONAL STANDARD

**ISO 5832-3**

Fifth edition
2021-11

# Implants for surgery — Metallic materials —

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



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



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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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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).



This fifth edition cancels and replaces the fourth edition (ISO 5832-3:2016), which has been technically revised.

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

— normative references have been updated;

— requirements for microstructure have been clarified in Clause 5;

— the pass/fail criteria for tensile testing of material properties have been clarified in 6.1;

— Table 3 on test methods has been updated;

— references to ISO 20160 and EN 3114-03 have been removed from Annex A.

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

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with 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 applications. However, this document covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.