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# Kirurgiske implantater – Metalliske materialer – Del 2: Ulegeret titan

Implants for surgery – Metallic materials – Part 2: Unalloyed titanium (ISO 5832-2:2018)

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EUROPÄISCHE NORM

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English Version

## Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:2018)

Implants chirurgicaux - Produits à base de métaux  
- Partie 2: Titane non allié (ISO 5832-2:2018)

Chirurgische Implantate - Metallische Werkstoffe  
- Teil 2: Unlegiertes Titan (ISO 5832-2:2018)

This European Standard was approved by CEN on 1 March 2018.

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## Contents

Page

European foreword .....	3
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## European foreword

This document ([EN ISO 5832-2:2018](#)) 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of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.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 5832-2:2012](#).

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

### Endorsement notice

The text of [ISO 5832-2:2018](#) has been approved by CEN as [EN ISO 5832-2:2018](#) without any modification.

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# **Implants for surgery — Metallic materials —**

## **Part 2: Unalloyed titanium**

*Implants chirurgicaux — Produits à base de métaux —  
Partie : Titane non allié*



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## Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Chemical composition</b> .....	<b>1</b>
<b>5 Microstructure</b> .....	<b>2</b>
<b>6 Mechanical properties</b> .....	<b>2</b>
6.1 Tensile properties.....	2
6.2 Bending properties.....	2
<b>7 Test methods</b> .....	<b>3</b>

This is a preview of "DS/EN ISO 5832-2:201...". Click here to purchase the full version from the ANSI store.

## 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](http://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 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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, SC 1, *Materials*.

This fourth edition cancels and replaces the third edition ([ISO 5832-2:1999](http://www.iso.org/iso/5832-2:1999)), which has been technically revised.

A list of all parts in the [ISO 5832 series](http://www.iso.org/iso/5832-series) can be found on the ISO website.

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## Introduction

No known surgical implant material has ever been shown to cause absolutely no adverse reaction 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 applications.

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# Implants for surgery — Metallic materials —

## Part 2: Unalloyed titanium

### 1 Scope

This document specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Six grades of titanium based on tensile strength are listed in [Table 2](#).

NOTE — The mechanical properties of a sample obtained from a finished product made of this metal 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 6892-1](#), *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

[ISO 7438](#), *Metallic materials — Bend test*

[ASTM E112](#), *Standard test methods for determining average grain size*