Norma Española

UNE-EN ISO 5840-3:2021

Idioma: Inglés

Implantes cardiovasculares. Prótesis de válvulas cardíacas. Parte 3: Válvulas cardiacas de sustitución implantadas por técnicas transcatéter. (ISO 5840-3:2021). (Ratificada por la Asociación Española de Normalización en marzo de 2021.)

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Implantes cardiovasculares. Prótesis de válvulas cardíacas. Parte 3: Válvulas cardiacas de sustitución implantadas por técnicas transcatéter. (ISO 5840-3:2021). (Ratificada por la Asociación Española de Normalización en marzo de 2021.)

Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques (ISO 5840-3:2021) (Endorsed by Asociación Española de Normalización in March of 2021.)

Implants cardiovasculaires - Prothèses valvulaires - Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter (ISO 5840-3:2021) (Entérinée par l'Asociación Española de Normalización en mars 2021.)

En cumplimiento del punto 11.2.5.4 de las Reglas Internas de CEN/CENELEC Parte 2, se ha otorgado el rango de documento normativo español UNE al documento normativo europeo EN ISO 5840-3:2021 (Fecha de disponibilidad 2021-02-03)

Este documento está disponible en los idiomas oficiales de CEN/CENELEC/ETSI.

Este anuncio causará efecto a partir del primer día del mes siguiente al de su publicación en la revista UNE.

La correspondiente versión oficial de este documento se encuentra disponible en la Asociación Española de Normalización (Génova 6 28004 MADRID, www.une.org).

Las observaciones a este documento han de dirigirse a:

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EUROPEAN STANDARD
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English Version

Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques (ISO 5840-3:2021)

Implants cardiovasculaires - Prothèses valvulaires - Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter (ISO 5840-3:2021)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 3: Durch minimal-invasive Methoden implantierter Herzklappenersatz (ISO 5840-3:2021)

This European Standard was approved by CEN on 22 September 2020.

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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

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European foreword

This document (EN ISO 5840-3:2021) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with 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 August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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 5840-3:2013.

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 5840-3:2021 has been approved by CEN as EN ISO 5840-3:2021 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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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 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 5840-3:2013), which has been technically revised.

The main changes compared to the previous edition are as follows: the engineering and clinical requirements in the ISO 5840 series have been updated to current specifications and integrated and harmonized across all parts.

A list of all parts in the ISO 5840 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.