

Implantes cardiovasculares. Prótesis de válvulas cardíacas. Parte 3: Válvulas cardíacas de sustitución implantadas por técnicas transcáteter. (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 cardíacas de sustitución implantadas por técnicas transcáteter. (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.)*

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## Asociación Española de Normalización

Génova, 6  
28004 MADRID-España  
Tel.: 915 294 900  
[info@une.org](mailto:info@une.org)  
[www.une.org](http://www.une.org)

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

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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of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.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

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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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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](http://www.iso.org/members.html).