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Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products

Part 1: General requirements

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This British Standard is the UK implementation of EN ISO 12417-1:2015. It supersedes DD ISO/TS 12417:2011 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements (ISO 12417-1:2015)

Implants cardiovasculaires et circuits extra-corporels - Produits de combinaison médicament-dispositif vasculaire - Partie 1: Exigences générales (ISO 12417-1:2015)

Kardiovaskuläre Implantate und extrakorporale Systeme - Vaskuläre Medizinprodukt/Arzneimittel-Kombinationsprodukte - Teil 1: Allgemeine Anforderungen (ISO 12417-1:2015)

This European Standard was approved by CEN on 8 August 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

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European foreword

This document (EN ISO 12417-1:2015) 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 April 2016, and conflicting national standards shall be withdrawn at the latest by April 2016.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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 12417-1:2015 has been approved by CEN as EN ISO 12417-1:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

This standard provides a process for managing risks associated with medical devices. Because this standard describes an ongoing process applicable in part or in all to the Essential Requirements of Directive 93/42/EEC on medical devices, it is not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed. For particular medical devices or for particular safety aspects, additional specific requirements may need to be complied with in order to meet the essential requirements. With respect to users of medical devices and third persons, additional specific requirements from other EU Directives may need to be complied with in order to meet Essential Requirement 1. Relevant harmonized standards may also be used for these purposes.

The risk management processes described in this standard could establish the need for collection of clinical or other experimental data for risk-benefit evaluation purposes. It does not describe how this has to be carried out. Relevant harmonized standards may be used for this purpose.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this standard.

Table ZA.1— Correspondence between this European Standard and Directive 93/42/EEC amended by Directive 2007/47/EEC

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 12417-1	Qualifying remarks
7.1	Clause 5 Clause 8	
7.2	Clause 8 9.3 Clause 10	
7.3	7.2.4.3 7.2.4.3.2 7.2.4.3.2 g) 7.2.4.3.5	

Essential Requirements (ERs) of Directive 93/42/EEC	**Clause(s)/sub-clause(s) of this EN ISO 12417-1**	**Qualifying remarks**
7.4	7.2.4.3 7.2.4.3.4 7.2.4.3.10 7.2.4.3.12 7.2.4.3.13	
7.5	7.2.4.3.4 7.2.4.3.10 7.2.4.3.11 7.2.4.3.16 9.3	
7.6	5.2.3 f)	
8.1	Clause 9 Clause 10	
8.3 (Design)	5.1 7.2.4.2	
8.3 (Manufacturing, Packaging)	Clause 8 Clause 9 10.1 10.2 11.2 m)	
8.4	9.1.1	
8.5	8.1 9.2	
8.6	9.2 Clause 10	
8.7	Clause 11	EN ISO 14630:2012, 11.2 f)
9.1	5.1 a) 5.2.3 e) 7.2.4.3.10	See specific standards product requirements for the device part
9.2 (Risk of injury)	5.1 7.2.4.1	
9.2 (Magnetic fields)	5.2.2 f) 5.2.3 g) 7.2.4.3.7	
9.2 (Aging)	5.2.1 e) 5.2.2 a) 7.1 7.2.4.3.10	
9.3	11.2.1 l)	

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 12417-1	Qualifying remarks
13.1	11.2.1 i) 11.3	
13.2	Clause 11	
13.3 a)	11.2.1 b)	
13.3 b)	11.2.1 a), c), d)	
13.3 c)	11.2.1 f)	
13.3 d)	11.2.1 e)	
13.3 e)	11.2.1 h)	
13.3 f)	11.2.1 g)	
13.3 i)	11.2.1 k)	
13.3 j)	11.2.1 i)	
13.3 k)	11.2.1 j)	
13.3 l)	11.2.1 l)	
13.3 m)	11.2.1 f)	
13.4	11.3 a), d)	
13.5	Clause 11	
13.6 a)	11.3	
13.6 b)	11.3 e), g), j), k), r)	
13.6 c)	N/A	See EN ISO 14630, 11.3 f)
13.6 e)	11.2 b), e), i), j), k), m)	
13.6 f)	11.3 j)	
13.6 g)	11.3 o), q)	
13.6 l)	11.3 j)	
13.6 m)	11.3 a), b), c), f)	
13.6 n)	11.3 k)	
13.6 q)	11.3 t)	

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

ISO 12417 consists of the following parts under the general title, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products*:

— *Part 1: General requirements*

— *Part 2: Local regulatory guidance*

Introduction

This part of ISO 12417 was prepared in order to provide minimum requirements for vascular device-drug combination products (VDDCPs).

Only issues related to vascular devices combined with drug(s), wherein the drug serves an ancillary function of the VDDCP are covered by this part of ISO 12417.

It was impossible, when writing this part of ISO 12417, to take into consideration all future and emerging technologies. VDDCPs using such technologies will need to be evaluated following the basic requirements of this International Standard. Testing beyond the scope of this part of ISO 12417 might also be necessary to characterize these device systems. Consideration shall be given to the failure modes of the VDDCP and their effects on the performance in deciding what testing will be appropriate.

For issues related to the primary mode of action (PMOA) of the vascular VDDCP, the reader might find it useful to consider a number of other International Standards (see Bibliography).

Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products —

Part 1: General requirements

1 Scope

This part of ISO 12417 specifies requirements for vascular device-drug combination products (VDDCPs) based upon current technical and medical knowledge. VDDCPs are medical devices with various clinical indications for use in the human vascular blood system. A VDDCP incorporates, as an integral part, substance(s) which, if used separately, can be considered to be a medicinal substance or product (drug substance, drug product) but the action of the medicinal substance is ancillary to that of the device and supports the primary mode of action (PMOA) of the device. With regard to safety, this part of ISO 12417 outlines requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer. For implanted products, this International Standard should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants. This International Standard should also be considered as a supplement to relevant device-specific standards, such as the ISO 25539-series specifying requirements for endovascular devices. Requirements listed in this part of ISO 12417 also address VDDCPs that are not permanent implants.

NOTE Due to variations in the design of combination products covered by this part of ISO 12417 and due to the relatively recent development of some of these combination products, acceptable standardized *in vitro* test results and clinical study results are not always available. As further scientific and clinical data become available, appropriate revision of this part of ISO 12417 might be necessary.

Delivery systems or parts of the delivery system are included in the scope of this part of ISO 12417, if they comprise an integral component of the vascular device and if they are drug-covered (e.g. drug-covered balloon catheters and drug-covered guidewires).

Devices whose PMOA is to provide a conduit for delivery of a drug, are excluded from the scope of this part of ISO 12417 (e.g. infusion catheters), unless they contain a drug component that is intended to have an ancillary action to the device part (e.g. antimicrobial coated infusion catheter).

Procedures and devices used prior to and following the introduction of the VDDCP (e.g. balloon angioplasty devices) are excluded from the scope of this part of ISO 12417 if they do not affect the drug-related aspects of the device.

This part of ISO 12417 is not comprehensive with respect to the pharmacological evaluation of VDDCPs. Some information on the requirements of different national and regional authorities is given in Annex B.

Absorbable components of VDDCPs (e.g. coatings) are addressed by this part of ISO 12417 in their connection with drug-related aspects of the device. Degradation and other time-dependent aspects of absorbable implants and coatings are not completely addressed by this part of ISO 12417.

NOTE See also ISO/TS 17137 and ASTM F3036-13.

This part of ISO 12417 does not address issues associated with viable or non-viable biological materials such as tissues, cells, or proteins.

This part of ISO 12417 does not address issues associated with active surgical implants (i.e. implants that require power not generated by the human body or gravity).