

Biological evaluation of medical devices

Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)

ICS 11.100.20

National foreword

This British Standard is the UK implementation of EN ISO 10993-9:December 2009. It supersedes BS EN ISO 10993-9:May 2009 which is withdrawn.

NOTE CEN issued two standards with the identifier EN ISO 10993-9 in 2009. The first, published in May 2009 was a revision of EN ISO 10993-9:2003 and reflected the changes to the EU Medical Devices Directive. The second, published in December 2009 was the European implementation of the full revision of ISO 10993-9:2003 and superseded the May 2009 publication, which has been withdrawn. BSI has included the month of the CEN publication in the identifier to distinguish between the two editions.

The UK participation in its preparation was entrusted to Technical Committee CH/194, Biological evaluation of medical devices.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments/corrigenda issued since publication

Date	Comments
31 July 2010	Correction to include the CEN month of publication in the identifier

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English Version

Biological evaluation of medical devices - Part 9: Framework for
identification and quantification of potential degradation products
(ISO 10993-9:2009)

Évaluation biologique des dispositifs médicaux - Partie 9:
Cadre pour l'identification et la quantification des produits
potentiels de dégradation (ISO 10993-9:2009)

Biologische Beurteilung von Medizinprodukten - Teil 9:
Rahmen zur Identifizierung und Quantifizierung von
möglichen Abbauprodukten (ISO 10993-9:2009)

This European Standard was approved by CEN on 18 November 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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Foreword

This document (EN ISO 10993-9:2009) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 "Biological evaluation of medical devices" the secretariat of which is held by NEN.

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 2010, and conflicting national standards shall be withdrawn at the latest by June 2010.

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 supersedes EN ISO 10993-9:2009.

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 Directives.

For relationship with EU Directives, see informative Annex ZA and ZB, which are integral parts 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 10993-9:2009 has been approved by CEN as a EN ISO 10993-9:2009 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 European Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this European Standard given in Table ZA.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on Medical devices

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC on Medical devices	Qualifying remarks/Notes
4, 5, Annex A	Annex I: 7.1, 7.2, 7.5	These relevant Essential Requirements are only partly addressed in this European Standard
NOTE Presumption of conformity depends on also complying with all relevant clauses/subclauses of ISO 10993-1.		

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

Annex ZB (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable 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 90/385/EEC on Active Implantable Medical Devices.

Once this European Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this European Standard given in Table ZB.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 90/385/EEC on Active Implantable Medical Devices

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC on Active Implantable Medical Devices	Qualifying remarks/Notes
4, 5, Annex A	Annex I: 9 (First and second indents only)	The first and second indents of this relevant Essential Requirement are only partly addressed in this European Standard
NOTE Presumption of conformity depends on also complying with all relevant clauses/subclauses of ISO 10993-1.		

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