



SLOVENSKI STANDARD
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Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2003)

Biologische Beurteilung von Medizinprodukten - Teil 3: Prüfungen auf Gentoxizität, Karzinogenität und Reproduktionstoxizität (ISO 10993-3:2003)

Évaluation biologique des dispositifs médicaux - Partie 3: Essais concernant la génotoxicité, la cancérogénicité et la toxicité sur la reproduction (ISO 10993-3:2003)

Ta slovenski standard je istoveten z: prEN ISO 10993-3

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 10993-3

November 2008

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Will supersede EN ISO 10993-3:2003

English Version

**Biological evaluation of medical devices - Part 3: Tests for
genotoxicity, carcinogenicity and reproductive toxicity (ISO
10993-3:2003)**

Évaluation biologique des dispositifs médicaux - Partie 3:
Essais concernant la génotoxicité, la cancérogénicité et la
toxicité sur la reproduction (ISO 10993-3:2003)

Biologische Beurteilung von Medizinprodukten - Teil 3:
Prüfungen auf Genotoxizität, Karzinogenität und
Reproduktionstoxizität (ISO 10993-3:2003)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 206.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

The text of ISO 10993-3:2003 has been prepared by Technical Committee ISO/TC 194 “Biological evaluation of medical devices” of the International Organization for Standardization (ISO) and has been taken over as prEN ISO 10993-3:2008 by Technical Committee CEN/TC 206 “Biological evaluation of medical devices” the secretariat of which is held by NEN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 10993-3:2003.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

Endorsement notice

The text of ISO 10993-3:2003 has been approved by CEN as a prEN ISO 10993-3:2008 without any modification.

Annex ZA (Informative)

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

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 given in Table ZA.1 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.

Table ZA.1 – Correspondence between this European Standard and EU Directives

| Clause(s)/sub-clause(s) of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|------------------------------------|---|--------------------------|
| 4, 5, 6, 7 | Annex I: 7.1, 7.2, 7.5 | |

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

INTERNATIONAL
STANDARD

ISO
10993-3

Second edition
2003-10-15

**Biological evaluation of medical
devices —**

Part 3:
**Tests for genotoxicity, carcinogenicity
and reproductive toxicity**

Évaluation biologique des dispositifs médicaux —

*Partie 3: Essais concernant la génotoxicité, la cancérogénicité et la
toxicité sur la reproduction*



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