

# norm

# NEN-EN-ISO 10993-16

Biological evaluation of medical devices -  
Part 16: Toxicokinetic study design for  
degradation products and leachables  
(ISO/DIS 10993-16:2008, IDT)

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EUROPEAN STANDARD  
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EUROPÄISCHE NORM

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Will supersede EN ISO 10993-16:1997

English Version

**Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO/DIS 10993-16:2008)**

Évaluation biologique des dispositifs médicaux - Partie 16: Conception des études toxicocinétiques des produits de dégradation et des substances relargables (ISO/DIS 10993-16:2008)

Biologische Beurteilung von Medizinprodukten - Teil 16: Entwurf und Auslegung toxikokinetischer Untersuchungen hinsichtlich Abbauprodukten und Extrakten (ISO/DIS 10993-16:2008)

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## Foreword

This document (prEN ISO 10993-16:2008) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 10993-16:1997.

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(s).

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## Biological evaluation of medical devices —

Part 16:

## Toxicokinetic study design for degradation products and leachables

*Évaluation biologique des dispositifs médicaux —**Partie 16: Conception des études toxicocinétiques des produits de dégradation et des substances relargables*

[Revision of first edition (ISO 10993-16:1997)]

ICS 11.100.20

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