

Biological evaluation of medical devices

Part 17: Establishment of allowable limits for leachable substances

(ISO 10993-17:2002)

This standard has been prepared by the Technical Committee CTN 111 *Surgical and medical devices* the Secretariat of which is held by FENIN.



UNE-EN ISO 10993-17

Biological evaluation of medical devices

Part 17: Establishment of allowable limits for leachable substances
(ISO 10993-17:2002)

Evaluación biológica de productos sanitarios. Parte 17: Establecimiento de los límites permisibles para sustancias lixiviadas (ISO 10993-17:2002).

Évaluation biologique des dispositifs médicaux. Partie 17: Établissement des limites admissibles des substances relargables (ISO 10993-17:2002).

This standard is the official English version of EN ISO 10993-17:2009, which adopts ISO 10993-17:2002.

This standard was published as UNE-EN ISO 10993-17:2009, which is the definitive Spanish version.

The remarks to this document must be sent to:

Asociación Española de Normalización

Génova, 6

28004 MADRID-España

Tel.: 915 294 900

info@une.org

www.une.org

Depósito legal: M 29940:2018

© UNE 2018

Published by AENOR INTERNACIONAL S.A.U. under licence of Asociación Española de Normalización.
Forbidden reproduction

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-17

April 2009

ICS 11.100.20

Supersedes EN ISO 10993-17:2002

English Version

**Biological evaluation of medical devices - Part 17: Establishment
of allowable limits for leachable substances (ISO 10993-
17:2002)**

Évaluation biologique des dispositifs médicaux - Partie 17:
Établissement des limites admissibles des substances
relargables (ISO 10993-17:2002)

Biologische Beurteilung von Medizinprodukten - Teil 17:
Nachweis zulässiger Grenzwerte für herauslösbare
Bestandteile (ISO 10993-17:2002)

This European Standard was approved by CEN on 12 April 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.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels