
Biološko ovrednotenje medicinskih pripomočkov - 23. del: Preskusi draženja - Dopolnilo A1: Dodatni in vitro modeli rekonstruirane človeške povrhnjice (ISO 10993-23:2021/Amd 1:2025)

Biological evaluation of medical devices - Part 23: Tests for irritation - Amendment 1: Additional in vitro reconstructed human epidermis models (ISO 10993-23:2021/Amd 1:2025)

Biologische Beurteilung von Medizinprodukten - Teil 23: Prüfungen auf Irritation - Änderung 1 (ISO 10993-23:2021/Amd 1:2025)

Évaluation biologique des dispositifs médicaux - Partie 23: Essais d'irritation - Amendement 1: Modèles supplémentaires d'épiderme humain reconstruit in vitro (ISO 10993-23:2021/Amd 1:2025)

[SIST EN ISO 10993-23:2021/A1:2025](https://standards.iteh.ai/catalog/standards/sist/3ad00ebc-5c78-46b5-a552-830092b95a4a/sist-en-iso-10993-23-2021-a1-2025)

Ta slovenski standard je istoveten z: EN ISO 10993-23:2021/A1:2025

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices
-----------	---	--

SIST EN ISO 10993-23:2021/A1:2025 en,fr,de

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

**EN ISO 10993-
23:2021/A1**

August 2025

ICS 11.100.20

English Version

**Biological evaluation of medical devices - Part 23: Tests for
irritation - Amendment 1: Additional in vitro
reconstructed human epidermis models (ISO 10993-
23:2021/Amd 1:2025)**

Évaluation biologique des dispositifs médicaux - Partie
23: Essais d'irritation - Amendement 1: Modèles
supplémentaires d'épiderme humain reconstruit in
vitro (ISO 10993-23:2021/Amd 1:2025)

Biologische Beurteilung von Medizinprodukten - Teil
23: Prüfungen auf Irritation - Änderung 1 (ISO 10993-
23:2021/Amd 1:2025)

This amendment A1 modifies the European Standard EN ISO 10993-23:2021; it was approved by CEN on 19 January 2025.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels