



SLOVENSKI STANDARD
SIST EN ISO 10993-23:2021/oprA1:2024
01-november-2024

Biološko ovrednotenje medicinskih pripomočkov - 23. del: Preskusi draženja - Dopolnilo A1: Dodatni in vitro modeli rekonstruirane človeške povrhnjice (ISO 10993-23:2021/DAmD1:2024)

Biological evaluation of medical devices - Part 23: Tests for irritation - Amendment 1: Additional in vitro reconstructed human epidermis models (ISO 10993-23:2021/DAmD1:2024)

Biologische Beurteilung von Medizinprodukten - Teil 23: Prüfungen auf Irritation - ÄNDERUNG 1 (ISO 10993 23:2021/DAmD1:2024)

Évaluation biologique des dispositifs médicaux - Partie 23: Essais d'irritation - Amendement 1: Modèles supplémentaires d'épiderme humain reconstruit in vitro (ISO 10993-23:2021/DAmD1:2024)

Ta slovenski standard je istoveten z: EN ISO 10993-23:2021/prA1

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices
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SIST EN ISO 10993-23:2021/oprA1:2024 en,fr,de



DRAFT Amendment

ISO 10993-23:2021/ DAM 1

Biological evaluation of medical devices —

Part 23: Tests for irritation

AMENDMENT 1: Additional in vitro reconstructed human epidermis models

ICS: 11.100.20

ISO/TC 194

Secretariat: DIN

Voting begins on:
2024-09-25

Voting terminates on:
2024-12-18

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Published in Switzerland

ISO 10993-23:2021/DAM 1:2024(en)

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Amendment 1 to ISO 10993-23:2021 was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biocompatibility of medical and dental materials and devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This amendment to ISO 10993-23:2021 refines the following:

- Addition of two reconstructed human epidermis (RhE) models to the list of models accepted to conduct in vitro alternative test per the methods in 6.2 to 6.12;
- Clause 6 updated to introduce specificities of the two RhE models added.

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