



**SLOVENSKI STANDARD**  
**SIST EN ISO 10993-12:2021/oprA1:2024**  
**01-september-2024**

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**Biološko ovrednotenje medicinskih pripomočkov - 12. del: Priprava vzorcev in referenčni materiali - Dopolnilo A1 (ISO 10993 12:2021/DAM 1:2024)**

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials - Amendment 1 (ISO 10993 12:2021/DAM 1:2024)

Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien - ÄNDERUNG 1 (ISO 10993 12:2021/DAM 1:2024)

Évaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et matériaux de référence - Amendement 1 (ISO 10993 12:2021/DAM 1:2024)

**Ta slovenski standard je istoveten z: EN ISO 10993-12:2021/prA1**

**ICS:**

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices
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**SIST EN ISO 10993-12:2021/oprA1:2024 en,fr,de**





# DRAFT Amendment

## ISO 10993-12:2021/ DAM 1

### Biological evaluation of medical devices —

#### Part 12: Sample preparation and reference materials

#### AMENDMENT 1

*Évaluation biologique des dispositifs médicaux —*

*Partie 12: Préparation des échantillons et matériaux de référence*

*AMENDEMENT 1*

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ISO/TC 194

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## ISO 10993-12:2021/DAM 1:2024(en)

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

This amendment to ISO 10993-12:2021 refines the following:

- the way in which ISO 14971 (in clause 4), ISO 10993-1 (in clause 7) and ISO 10993-18 and ISO/TS 10993-19 (in 10.1) are referenced and thus the inclusion of these standards in clause 2;
- change of Table 1;
- deletion of a sentence in 10.3.4.

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