
**Biological evaluation of medical
devices —**

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

Évaluation biologique des dispositifs médicaux —

Partie 12: Préparation des échantillons et matériaux de référence



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Foreword

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This fifth edition cancels and replaces the fourth edition (ISO 10993-12:2012), which has been technically revised.

The main changes compared to the previous edition are as follows:

- change of scope to cover extractions only for biological evaluation tests;
- harmonization of definitions with ISO 10993-18;
- revision of [10.3.1](#) extraction condition table and [Annex D](#) regarding exhaustive extraction.

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