



BSI Standards Publication

Biological evaluation of absorbable medical devices

Part 1: General requirements

National foreword

This Published Document is the UK implementation of ISO/TS 37137-1:2021.

The UK participation in its preparation was entrusted to Technical Committee CH/194, Biological evaluation of medical devices.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2021

ISBN 978 0 539 02157 8

ICS 11.040.40

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 March 2021.

Amendments/corrigenda issued since publication

Date	Text affected
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TECHNICAL
SPECIFICATION

ISO/TS
37137-1

First edition
2021-03-12

**Biological evaluation of absorbable
medical devices —**

Part 1:
General requirements

*Évaluation biologique des dispositifs médicaux résorbables —
Partie 1: Exigences générales*



Reference number
ISO/TS 37137-1:2021(E)



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

A list of all parts in the ISO 37137 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Absorbable implants are intentionally designed to degrade and therefore release degradation products into the patient, a feature making these products fundamentally different from other medical devices that are not intended to be absorbed by the patient's body.

The provided content is intended to describe potential approaches to perform biological evaluation of absorbable implants to support the safety of such absorbable medical devices.

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Biological evaluation of absorbable medical devices —

Part 1: General requirements

1 Scope

This document specifies the requirements for the evaluation of absorbable medical devices during a biological risk assessment based on ISO 10993-1, including a clarification of the terms "absorb", "degrade" and other related terms (see [Annex A](#)).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993 (all parts), *Biological evaluation of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

NOTE For further discussion of utilized terminology and for a list of potential terms to be included in a literature search see [Annex A](#).

3.1

absorb

absorption

<biomaterials> action of a non-endogenous (foreign) material or substance, or its decomposition products passing through or being assimilated by either cells or tissue, or both over time

[SOURCE: ISO 10993-6:2016, 3.1]

3.2

degradation product

intermediate or final substance which results from the physical, metabolic, and/or chemical decomposition of a material or agent

3.3

degrade

physically, metabolically, and/or chemically decompose a material or substance