ICS 11.100.20
CCS C 30

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 48011-2026

Absorbable/resorbable biomaterials with a density differing from the surrounding tissue - Determination of biodegradation in vivo - X-ray microCT test method

具有组织密度差的可吸收生物材料 体内降解率测定 X射线显微CT法

Issued on: July 2, 2026 **Implemented on: August 1, 2027**

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Standardization Administration of the PRC

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Foreword

This document was issued on 2 July 2026 by the State Administration for Market Regulation and the Standardization Administration of the People's Republic of China, and takes effect on 1 August 2027.

It is the first edition of this standard.

The document is under the responsibility of the National Medical Products Administration.

Classification: ICS 11.100.20, CCS C 30.

1 Scope

GB/T 48011-2026 is the Chinese national standard covering how the in-vivo degradation of a resorbable implant is measured by micro-CT - the implant is imaged over time inside the tissue and its remaining volume followed, which works precisely because its density differs from the tissue around it. It fixes the specimen and animal model, the imaging parameters, the segmentation and the calculation of the degradation rate. First edition, in force from 1 August 2027, under the National Medical Products Administration. It was issued on 2 July 2026 and takes effect on 1 August 2027, as a first edition. The document is under the responsibility of the National Medical Products Administration. This page is published from the official record of the 2026 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

2 Edition and transition

GB/T 48011-2026 is the first edition of this standard. It was issued on 2 July 2026 and takes effect on 1 August 2027.

There is no earlier edition to compare it with, so a specification that has to refer to this

subject can only cite GB/T 48011-2026 itself.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up documentation before the new text becomes the one that applies. The date on this page is the official one from the record of the Standardization Administration.

3 Classification and status

GB/T 48011-2026 is classified under ICS 11.100.20, in the field of health care technology. ICS is the International Classification for Standards, the same scheme used by ISO and by the national bodies of most countries, which is what allows a Chinese standard to be placed beside its foreign counterparts on subject rather than on number.

Its Chinese Standard Classification code is CCS C 30. CCS is the domestic scheme, a letter for the sector and two digits for the subject within it, and it is the code by which the standard is filed and searched in China.

The GB/T prefix marks a recommended national standard. It is not, in itself, law: it becomes binding when a contract names it, when a regulation or a mandatory standard refers to it, or when a producer declares conformity with it. In practice that covers most of the cases in which it will be read - a purchase specification, an inspection agreement or a certification scheme.

The document is under the responsibility of the National Medical Products Administration, which is the body that maintains it and that will answer a formal question about its interpretation.

4 Structure of the document

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

GB/T 48011-2026 runs to 15 pages in the English translation. What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both languages.

5 The English edition

The English edition of GB/T 48011-2026 is a full translation of the official Chinese text, not a summary, an abstract or a machine rendering left unchecked. Clause and subclause numbers, table and figure numbers and annex letters are those of the original, because they are what a specification, a purchase order or a test report cites.

Technical terms are translated against the vocabulary standards of the same field, so that a term used in GB/T 48011-2026 reads the same way as in the other Chinese standards it is used beside. Where a term has an established English form in an ISO or IEC document on the same subject, that form is used; where China's term has no foreign counterpart, it is translated literally and the Chinese is kept alongside it rather than replaced by an approximation.

Quantities, units and symbols are carried over unchanged. Chinese standards use SI, so a value in the translation is the value in the original document, not a conversion, and a limit read from the English text is the limit that will be applied by a Chinese inspection body reading the Chinese one.

This page is compiled from the official publication record: the standard number and both titles, the issuing bodies, the dates of issue and effect, the edition it replaces, and the ICS and CCS classification. The requirements, limits, tables and test conditions are in the document itself.