



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0268-2008

**Dentistry - Biological evaluation of medical devices used in
dentistry - Unit 1: Evaluation and testing**

牙科学 口腔医疗器械生物学评价 第1单元：评价与试验

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Foreword

This document was issued on 25 April 2008 by the National Medical Products Administration and takes effect on 1 December 2009.

It is a YY/T standard: it is recommended rather than compulsory, but it is the method a Chinese reviewer applies when assessing a registration submission.

1 Scope

YY/T 0268 is the biological evaluation standard for dental devices in China. Dentistry is treated separately from general medical device biocompatibility because the exposure is unlike anything else: materials sit permanently in the mouth in contact with saliva, mucosa, dentine and sometimes pulp, they are placed in the mouth as unset chemistry that finishes curing there, and the patient swallows whatever leaches out. This unit covers the evaluation approach and the tests, selecting from the general biological evaluation methods the ones appropriate to those exposures. For a manufacturer of dental materials or devices seeking Chinese registration, this is the standard the biological evaluation plan and report are built on.

About this edition

YY/T 0268-2008 is the current edition. It was issued on 25 April 2008 and has been in force since 1 December 2009.

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.

Classification and status

The YY/T prefix marks an industry standard, issued by the authority for its sector rather than by the national body. It applies within that industry, and it becomes binding in the same ways a recommended national standard does: when a contract, a regulation or a declaration of conformity names it.

How a Chinese national standard is set out

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.

YY/T 0268-2008 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.

About this English translation

The English edition of YY/T 0268-2008 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 YY/T 0268-2008 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 requirements, limits, tables and test conditions are in the document itself.

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