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

YY/T 0127.4-2009

**Biological evaluation of medical devices used in dentistry - Part
2: Test method - Bone implant test
(English Translation)**

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Foreword

This Standard is one of the series standards of "Dental Medical device Biology Assessment".

The 1st unit, YY/T 0268.2008 "Dentistry. Biological evaluation of medical devices used in dentistry. Part 1.Evaluation and test" of Dental Medical device Biology Assessment series standards, is an option for dental medical device biology assessment and test items; it is a guideline standard.

The 2nd unit of the series standards is "Dental medical devices specific biological test methods". It is divided into the following sections.

2 YY/T 0127.2-2009 Biological evaluation of medical devices used in dentistry. Part 2.

Test method. Acute systemic toxicity. intravenous path

3 YY/T 0127.3-1998 Biological evaluation of dental materials - Unit 2.Biological

evaluation method of dental materials - Endodontic usage test

4 YY/T 0127.4-2009 Biological evaluation of medical devices used in dentistry. Part 2.

Test method Bone implant test

5 YY/T 0127.5-1999 Biological evaluation of dental materials - Unit 2.Biological test

methods of dental materials - Inhalation toxicity test

6 YY/T 0127.6-1998 Biological evaluation of dental materials - Unit 2.Biological test

methods of dental materials - Dominant lethal test

7 YY/T 0127.7-2001 Biological evaluation of dental materials. Part 2.Biological evaluation

test method of dental materials. Pulp and dentine usage test

8 YY/T 0127.8-2001 Biological evaluation of dental materials. Part 2.Biological evaluation

test method of dental materials. Subcutaneous implant test

9 YY/T 0127.9-2009 Biological evaluation of medical devices used in dentistry. Part 2.

Test method - Cytotoxicity tests. Agar diffusion test and filter diffusion test

10 YY/T 0127.10-2009 Biological evaluation of medical devices used in dentistry. Part 2.

Test method. Salmonella typhimurium reverse mutation assay (Ames mutagenicity test)

11 YY/T 0127.11-2001 Dentistry - Preclinical evaluation of biocompatibility of medical

devices used in dentistry. Part 2.Biological evaluation test method of dental materials - Pulp capping test

12 YY/T 0127.12-2008 Dentistry. Biological evaluation of medical devices used in

dentistry Part 2.Test method - Micronucleus test

13 YY/T 0127.13-2009 Dentistry. Biological evaluation of medical devices used in

dentistry Part 2.Test method - Micronucleus test

14 YY/T 0244-1996 Biological test methods of dental materials - Short term systemic

toxicity test. dental route

15 YY/T 0127.14-2009 Biological evaluation of medical devices used in dentistry. Part 2.

Test method. Acute oral toxicity test

16 YY/T 0127.15-2009 Biological evaluation of medical devices used in dentistry. Part 2.

Test method Subacute and subchronic toxicity test - Oral route

This Standard is Part 4 of YY/T 0127 series standards.

This Standard is the revised version of YY/T 0127.4-1998 "Biological evaluation of medical devices used in dentistry. Part 2.Test method Bone implant test". During the drafting process, it references to the ISO 10993.6-2007 "Biological evaluation of medical devices - Part 6.Tests for local effects after implantation". Test principles of ISO 10993.6-2007 are applicable to this Standard.

Compared with the standard YY/T 0127.4-1998, the main changes are as follows.

- Standard name is renamed as. "Biological evaluation of medical devices used in dentistry. Part 2. Test method Bone implant test".
- 3.1 Sample preparation adds samples with different types of materials. The sample quantity number of each test cycle is changed to at least 10.
- 3.2, 4, 5, 6 add a variety of options.
- 7 During surgical procedure, "25g/L iodine and 75% ethanol" are changed to "5g/L iodine".
- 10 Biological evaluation is modified.
- ADD Appendix A.

Appendix A is an informative appendix.

From the date of implementation, this Standard will replace the obsolete Y/T 0217.4-1998 "Biological evaluation of medical devices used in dentistry. Part 2. Test method - Bone implant test".

This Standard was proposed by the State Food and Drug Administration.

This Standard is administered by the National Dental Materials and Appliances Equipment Standardization Technical Committee (SAC/TC 99).

This Standard was responsibly drafted by Dental Medical Device Inspection Center, School of Stomatology of Peking University.

1 Scope

This Standard specifies the test method of bone implantation of dental medical devices.

This Standard shall be used to evaluate the biological reactions of bone tissue of which the dental bone issue is planned to contact with dental medical devices in long-term.

2 Normative References

The articles contained in the following documents have become part of this Standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest edition shall be applicable to this Standard.

GB/T 13810 Wrought titanium and titanium alloy for surgical implants