

ICS 11.060.20
CCS C33

YY

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

YY/T 0803.4-2015

**Dentistry - Root-canal instruments - Part 4: Auxiliary
instruments**

牙科学 根管器械 第4部分：辅助器械

Issued on: March 2, 2015

Implemented on: January 1, 2016

Issued by: National Medical Products Administration

Table of Contents

1 Scope	1
2 Normative references	1
3 Terms, definitions and symbols	1
4 Category	2
2 Sampling 6	9
7 Test 9 8 names, logos and identifying 10 9 package	10
10 References	11

Foreword

YY/T 0803 "Dentistry endodontic instruments" by the following five components.

--- Part 1. General requirements and test methods;

--- Part 2. Amplifier;

--- Part 3. pressurizer;

--- Part 4. assistive devices;

--- Part 5. Shaping and cleaning instruments. This section YY/T Section 40803 of. This section drafted in accordance with GB/T 1.1-2009 given rules. The partial modification of the use of ISO 3630-4.2009 "dentistry endodontic instruments - Part 4. Auxiliary instruments." This part of ISO 3630-4.2009 technical differences are as follows:

--- On normative references, this standard has been adjusted technical differences, in order to adapt our technical conditions, the adjusted situation Focus is reflected in the status of Chapter 2, "Normative references", the specific adjustments are as follows: - with the GB/T 9937 (all parts) in place of the ISO 1942 (all parts); - with the modified use of international standards YY 0967.1-2015 replaces ISO 1797-1.1997; - with the modified use of international standards YY 0967.2-2015 replaces ISO 1797-2.1992; - equivalents adoption of international standards YY 0803.1-2010 replaces ISO 3630-1.2008; - with the modified use of international standards YY/T 0803.2-2010 instead of ISO 3630-2.2000; OK

--- this section "barb height" value of reference ISO 3630-1.1992 Table 5, Table 6, and Table 1 of this section See also ISO 3630-1.1992 joined the "nominal size" and "barbs height" is calculated relationship. Please note that some of the content of this document may involve patents. Issuer of this document does not assume responsibility for the identification of these patents. This part is proposed by the China Food and Drug Administration. This part of the National Dental Materials and Devices Equipment Standardization Technical

Committee dental equipment and instruments at the Technical Committee (SAC/TC99SC1) centralized. This section is drafted. Shenzhen speed Hang Technology Development Co., Ltd., the State Food and Drug Administration of Quality Supervision, Guangzhou Medical Devices Inspection Center, Hangzhou New Asia Dental Materials Co., Ltd. The main drafters of this section. Li Danrong, Wan Yiyi, Wang, Chen Xianming. Dentistry endodontic instruments - Part 4. Auxiliary equipment

1 Scope

YY/T 0803.4 is Part 4 of the Chinese root canal instrument series, covering the auxiliary instruments: the spreaders, pluggers, spiral fillers and the other tools that support the shaping and filling of a canal without doing the cutting themselves. Endodontic instruments are standardised in unusual dimensional detail because they work unseen inside a canal a fraction of a millimetre wide, and because a fractured instrument left in a canal is a complication with no easy remedy. The standard fixes the dimensions, materials and mechanical requirements together with the test methods. For a manufacturer or an importer of endodontic instruments serving the Chinese market, this is the standard the auxiliary instrument range is specified against.

YY/T 0803 provisions of this part of the YY 0803.1, YY 0803.2, YY 0803.3 and ISO 3630-5:2011 does not mention Requirements and test methods on the handheld or machine type endodontic instrument. This section provides device specifications, product identification, safety injection Precautions, instructions and labeling requirements.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 9937 (all parts) oral vocabulary [ISO 1942 (all parts)]

YY 0967.1-2015 lever dental rotary instruments - Part 1. metal rod (ISO 1797-1:1992, MOD)

YY 0967.2-2015 lever dental rotary instruments - Part 2. plastic rod (ISO 1797-2:1992, MOD) Part 1

YY 0803.1-2010 dentistry endodontic instruments. General requirements and test methods (ISO 3630-1:2008, IDT)

YY/T 0803.2-2010 dentistry endodontic instruments Part 2. Amplifier (ISO 3630-2:2000, MOD)

3.1 Terms and Definitions GB/T 9937

YY 0803.1-2010 defined and the following terms and definitions apply to this document and.

3.1.1 Barb needle barbedbroach pulpectomy Design barbed endodontic instruments for removing pulp soft tissue.

3.1.2 Rasp rasp The working portion having sharp protrusions, and thus friction can expand the root canal instruments.

3.1.3 Paste conveyor pastecarrier The filling material or drug delivery to the root canal instruments.

3.1.4 Endodontic probe root-canaexplorer For detecting root canal instruments.

3.1.5 Cotton Needle cottonbroach Used with cotton, dry root canal or place for medication in root canal endodontic instruments.

3.1.6 Barb height heightofbarb From the outside of the vertical distance down the stem to the hook tip.