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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0803.1-2010

Dentistry - Root canal instruments - Part 1: General requirements and test methods

牙科学 根管器械 第1部分：通用要求和试验方法

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Foreword

All technical contents of this Part are mandatory. YY 0803 consists of the following parts, under the general title Dentistry - Root-canal instruments. -- Part

1 Scope

YY 0803.1 sets the general requirements and test methods for root canal instruments, the files and reamers used to shape a root canal before it is filled. It is Part 1 of the Chinese series and carries what applies across the class: the dimensions and taper that define an instrument size, the resistance to fracture in torsion and in bending, the corrosion resistance, the handle marking and colour coding by size, and the sterilization. Instrument separation inside a canal is one of the commonest mishaps in endodontics and is often unretrievable, which is why the mechanical tests are the heart of the standard. Being a YY standard without the /T suffix, compliance is compulsory in China.

This part of YY 0803 specifies general requirements and test methods for root-canal instruments used for endodontic purposes, e.g. enlargers, shaping and cleaning instruments, condensers, and accessory instruments. In addition it covers general size designations, colour coding, packaging and identification symbols.

2 Normative references

The following documents, referenced by

YY 0803, are indispensable for the application of this document. For dated references, all subsequent amendments (not including errata content) or revisions do not apply to this Part. However, parties to agreements that are based on this Part are encouraged to study whether the latest versions of these documents can be used. For undated references, the latest edition applies to this Part.

GB/T 7408, Data elements and interchange formats - Information interchange - Representation of dates and times (GB/T 7408-2005, ISO 8601.2000, IDT)

GB/T 9937, Dentistry - Vocabulary (all parts) (GB/T 9937-2008, ISO 1942, IDT)

YY/T 0466.1, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part

3 Condensers; -- Part

4.Auxiliary instruments. This Part is Part 1 of YY 0803. This Part is identical to ISO 3630-1.2008 Dentistry - Root-canal instruments - Part 1. General requirements and test methods (English version). The main differences between this Part and ISO 3630-1.2008 are as follows: -- Make some editorial modifications in accordance with the requirements of GB/T 1.1; -- Delete the foreword of the international standard; -- For other international standards cited in this Part, if they have been converted into Chinese standards, replace the referenced international standard number with the corresponding national or industry standard number, and indicate the adoption relationship in Chapter 2 of this Part. This Part shall be under the jurisdiction of Subcommittee 1 on Dental Equipment and Devices of National Technical Committee 99 on Dental Materials and Equipment of Standardization Administration of China (SAC/TC 99/SC 1). Drafting organization of this Part. Guangzhou Medical Device Quality Supervision and Test Institute of the China Food and Drug Administration, Shenzhen Superline Technology Co., Ltd. Chief drafting staffs of this Part. Lu Wenjuan, Wu Yiming, Peng Canguang, Wang Zhong. Dentistry - Root-canal instruments - Part