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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0987.1-2016

Implants for Surgery - Magnetic Resonance Compatibility - Part 1: Safety Marking

外科植入物 磁共振兼容性

第 1 部分：安全标记

Issued on: March 23, 2016 **Implemented on: January 1, 2017**

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Foreword

YY/T 0987 Implants for Surgery - Magnetic Resonance Compatibility is divided into the following parts:

---Part 1: Safety Marking;

---Part 2: Magnetically Induced Displacement Force Test Method;

---Part 3: Evaluation of MR Image Artifacts from Passive Implants;

---Part 4: Radio Frequency Induced Heating on or near Passive Implants Test Method;

---Part 5: Magnetically Induced Torque Test Method.

This is the first part of YY/T 0987.

This Part was drafted in accordance with the rules in GB/T 1.1-2009.

This Part was formulated in accordance with the Act of Redrafting and ASTM F2503-2008 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

In comparison with ASTM F2503-2008, this Part has the following technical differences:

---In terms of the scope of application of the standard, this Part is also applicable to other medical devices or items that enter the magnetic resonance environment. If this Part conflicts with relevant laws and regulations, the laws and regulations shall prevail.

---In terms of normative references, this Part has made some adjustment with technical differences, so as to adapt to the technical conditions in China. The condition of such adjustment is intensively reflected in Chapter 2 “Normative References”. Please see the specific adjustment below:

- Use YY/T 0987.2 to replace ASTM F2052-06;
- Use YY/T 0987.3 to replace ASTM F2119-07;
- Use YY/T 0987.4 to replace ASTM F2182-11a;
- Use YY/T 0987.5 to replace ASTM F2213-06;
- Use GB/T 2893.1-2004 to replace ISO 3864-1: 2002.

---Use the table in Appendix A in GB/T 2893.1-2004 to replace Table 3;

---Delete Chapter 8 in ASTM F2503-2008.

Please be noted that certain contents in this document might involve patents. The institution that issues this document shall not undertake any responsibility of identifying these patents.

This Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee 110 on Implants for Surgery and Orthopedic Devices of Standardization Administration of China (SAC/TC 110).

The main drafting organizations of this Part: China Food and Drug Administration, Tianjin Medical Devices Quality Supervision and Testing Center, MicroPort Scientific Corporation (Shanghai).

The main drafters of this Part: Lijia, Miaohui, Li Libin, Sunbing, Shi Haifeng.

Implants for Surgery - Magnetic Resonance Compatibility - Part 1: Safety Marking

1 Scope

This Part of YY/T 0987 specifies safety marking of medical devices and other items in the magnetic resonance (MR) environment, so as to provide prompt message on safety.

NOTE 1: other than implants for surgery, other medical devices or items that enter the magnetic resonance environment can also refer to this Part for safety marking.

NOTE 2: If this Part conflicts with relevant laws and regulations, the laws and regulations shall prevail.

This Part has the following purposes:

(1) Suggest that an item, that might enter MR environment, should be permanently marked, so as to indicate whether this item is safe in MR environment;

(2) Suggest the information that shall be included in the marking.

Sometimes it is not realistic to directly mark on implants and certain medical devices. When it is impossible to directly mark on them, it is suggested to mark on labels and patients' information cards.

This Part does not include the content of image artifact, because artifact does not belong to the issue of safety.

This Part adopts numerical value under international system of units as the standard; numerical value in the brackets shall merely be considered as reference.

This Part does not attempt to elaborate all the involved safety questions, even though those safety questions are related with the usage. Determining appropriate safety and health specifications and clarifying the applicability of management limit before application is the responsibility on the users of this Standard.

2 Normative References

The following documents are indispensable to the application of this Standard. In terms of references with a specified date, only versions with a specified date are applicable to this Standard. The latest version (including all the modifications) of references without a specified date is also applicable to this Standard.

GB/T 2893.1-2004 Graphical Symbols - Safety Colors and Safety Signs - Part 1: