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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 16174.1-2015

**Implants for surgery-Active implantable medical devices-Part 1:
General requirements for safety, marking and for information to
be provided by the manufacturer**

手术植入物 有源植入式医疗器械 第1部分：安全、标记和制造商所提供信息的通用要求

(English Translation)

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020, Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents.

This document is Part 1 of GB 16174, Implants for surgery - Active implantable medical devices. The following parts have been published under GB 16174.

-- Part 1.General requirements for safety, marking and for information to be provided by the manufacturer;

-- Part 2.Cardiac pacemakers.

This document replaces GB 16174.1-2015 Implants for surgery - Active implantable medical devices - Part 1.General requirements for safety, marking and for information to be provided by the manufacturer. Compared with GB 16174.1-2015, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

- Change terms and definitions (see Clause 3; Clause 3 of the 2015 edition);
- Add general requirements for software (see 5.2);
- Add usability of non-implantable parts (see 5.3);
- Add data security and protection from harm caused by unauthorized information tampering (see 5.4);
- Add general requirements for risk management (see 5.5);
- Add misconnection of parts of the active implantable medical device (see 5.6);
- Add requirements for human blood or human plasma, and the authorized representative from the sales packaging (see 9.12, 9.14);
- Change the requirements for particle release (see 14.2; 14.2 of the 2015 edition);
- Change the requirements for electric neutrality (see 16.2; 16.2 of the 2015 edition);
- Add requirements for active implantable medical device intended to supply heat (see 17.2);
- Add requirements for the active implantable medical device that is intended to use a transcutaneous energy transfer system (see 19.6);
- Change the requirements for the exposure test to diagnostic levels of ultrasonic energy (see 22.1; Clause 22 of the 2015 edition);
- Add requirements for wearing an active implantable medical device for an MRI procedure (see 22.2);
- Change the test of the implantable connectors (see 23.6; 23.6 of the 2015 edition);
- Add the mechanical shock test (see 23.7);
- Add requirements for accompanying documentation (see 28.24~28.28, 28.30).

This document adopts ISO 14708-1:2014 Implants for surgery - Active implantable medical devices - Part 1. General requirements for safety, marking and for information to be provided by the manufacturer by modification.

The technical differences between this document and ISO 14708-1:2014 and their reasons are as follows.

-- Use the normative reference GB/T 2423.5-2019 to replace IEC 60068-2-

27.2008 (see 23.7) to adapt to our country's technical conditions;

-- Use the normative reference GB/T 2423.43-2008 to replace IEC 60068-2-

47.2005 (see 23.2) to adapt to our country's technical conditions;

-- Use the normative reference GB/T 2423.56-2018 to replace IEC 60068-2-

64.2008 (see 23.2) to adapt to our country's technical conditions;

-- Use the normative reference GB 9706.1-2020 to replace IEC 60601-1:2012

(see 5.1, 15.1, 16.1, 20.1, 23.1, 24.1) to adapt to our country's technical conditions;

-- Use the normative reference GB/T 7408.1-2023 to replace ISO 8601:2004

(see 9.6, 9.7) to adapt to our country's technical conditions;

-- Use the normative reference GB/T 16886.1 to replace ISO 10993-1 (see 14.3)

to adapt to our country's technical conditions;

-- Use the normative reference GB/T 19633.1 to replace ISO 11607-1 (see 12.1)

to adapt to our country's technical conditions;

-- Use the normative reference GB/T 42062-2022 to replace ISO 14971:2007

(see 5.5) to adapt to our country's technical conditions;

-- Use the normative reference YY/T 0664-2020 to replace IEC 62304:2006 (see

5.2, 19.3) to adapt to our country's technical conditions.

This document also makes the following editorial modifications.

Implants for surgery - Active implantable medical devices -

Part 1. General requirements for safety, marking and for

information to be provided by the manufacturer

1 Scope

This document specifies requirements that are generally applicable to active implantable medical devices.

This document is applicable to active implantable medical devices that are electrically powered and powered by other energy sources (for example by gas pressure or by springs), as well as to some non-implantable parts and accessories of the active implantable medical devices.

Note 1: For particular types of active implantable medical devices, these general requirements are supplemented or modified by the requirements of particular parts.

The tests that are specified in this document are type tests and are to be carried out on samples of an active implantable medical device to show compliance.

Note 2: The device that is commonly referred to as an active implantable medical device can be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 2423.5-2019, Environmental testing - Part 2. Test methods - Test Ea and guidance. Shock (IEC 60068-2-27:2008, IDT)

GB/T 2423.22-2012, Environmental testing - Part 2. Test methods - Test N. Change of temperature (IEC 60068-2-14:2009, IDT)

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