ICS 11.040.40
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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 16174.1-2024

Replacing 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

Issued on: August 23, 2024 **Implemented on: September 1, 2027**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

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1 Scope

The document lays down the general requirements for active implantable medical devices.

It applies to electrically powered active implantable medical devices, to active implantable medical devices driven by another energy source, for example gas pressure or a spring, and to certain non-implantable parts and accessories of active implantable medical devices.

Note 1 states that for a particular active implantable medical device these general requirements are supplemented or modified by the requirements of the relevant particular part.

The tests specified in the document are type tests, conformity being shown by testing samples of the active implantable medical device.

Note 2 states that what is usually called an active implantable medical device may be a single device, a combination of several devices, or one or more devices together with one or more accessories; not all of these parts need to be implanted wholly or in part, but where a non-implantable part or an accessory affects the safety or the performance of the implanted device, requirements have to be placed on those parts and accessories.

3 Terms and definitions

3.1 Active medical device: a medical device that relies on electrical energy, or on an energy source other than one generated directly by the human body or by gravity, to perform its function.

3.2 Active implantable medical device: an active medical device implanted into the human body, that is, implanted partly or wholly into the body by a surgical or a medical procedure, or introduced into a natural orifice by a medical intervention, and remaining in the body after the procedure. The note adds that such a device may be a single active medical device or a system made up of a set of parts and accessories, software included, that interact so as to achieve the performance intended by the manufacturer, and that not all of these parts or accessories need be required to be implanted partly or wholly into the body.

3.3 Beginning of service (BOS): the time at which a single marketable active implantable

medical device is first placed on the market by the manufacturer.

3.4 Catheter: a flexible tube whose distal end reaches a site in the body through a body lumen, normally used to convey some substance. The note adds that a catheter can be used together with an electrode lead.

3.5 Correct use: normal use without use error, taken from YY/T 1474-2016, 3.7.

3.6 End of service (EOS): the time at which the single extended service period ends, after which the performance can no longer be assured to meet the design specification.

3.7 Hand-held: the part of an active implantable medical device intended to be held in the hand during normal use, taken from GB 9706.1-2020, 3.37, modified.

3.8 Harm: injury or damage to the health of people, or damage to property or the environment, taken from GB/T 42062-2022, 3.3.

3.9 Hazard: a potential source of harm, taken from GB/T 42062-2022, 3.4.

3.10 Information security: the protection of information and information systems against unauthorised access, use, disclosure, disruption, modification or destruction, so as to provide confidentiality, integrity and availability.

3.39 Validation: confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been met, taken from YY/T 1474-2016, 3.26.

4 Symbols and abbreviations

Where the situation makes it suitable, symbols, abbreviations and identification colours may be used in the marking and in the accompanying documentation of an active implantable medical device.

The symbols, abbreviations and identification colours shall follow a unified international or professional standard, for example YY/T 0466.1-2023. Where no unified international or professional standard exists, the symbols, abbreviations and identification colours shall be described in the accompanying documentation.

Conformity is checked by inspection.

A note adds that the symbols used by a particular active implantable medical device are specified in the corresponding particular requirements part.

5 General requirements for active implantable medical devices

5.1 General requirements for non-implantable parts: except for those requirements superseded by this document or by the particular requirements, the non-implantable parts of an active implantable medical device connected to, or provided with, a power supply shall

meet the applicable requirements of GB 9706.1-2020 as determined by the risk analysis. A note adds that other subclauses of the document also call for compliance with certain subclauses of GB 9706.1-2020, and that this holds for unpowered non-implantable parts as well. Conformity is confirmed by reviewing the test reports and the risk analysis provided by the manufacturer.

5.2 General requirements for software: the software of an active implantable medical device, or software that is itself within the definition of an active implantable medical device, shall have its life cycle process activities designed and validated according to YY/T 0664-2020. Conformity is confirmed by assessing the software life cycle process and the verification report supplied by the manufacturer according to YY/T 0664-2020.

5.3 Usability of non-implantable parts: for parts connected to or provided with a power supply, the manufacturer shall address the risk of poor usability in the usability engineering process, including usability related to labelling, marking and documentation. For parts not connected to and not provided with a power supply, the non-implantable parts shall give sufficient usability for the risks arising from correct use and from use error to be acceptable. In both cases conformity is confirmed by assessing whether the manufacturer's documentation meets the acceptance criteria of the usability validation plan, see 5.9 of YY/T 1474-2016.

5.4 Data security and protection against harm caused by unauthorised alteration of information: when communication with the implanted part of an active implantable medical device takes place over a wireless channel, the manufacturer shall evaluate information security through the risk management process and shall adopt suitable risk control measures to protect the patient from harm. Conformity is confirmed by examining the risk management file.

5.5 General requirements for risk management: the manufacturer shall define and record, according to GB/T 42062-2022, the policy for determining acceptable risk and the acceptability of residual risk; shall establish and maintain a risk management file meeting GB/T 42062-2022 and the requirements of this document; and shall establish and maintain a risk management plan meeting the relevant requirements of GB/T 42062-2022, other than the plan relating to the collection and review of production and post production information, the risk management plan forming part of the risk management file. For the purposes of this document the risk management process shall include risk analysis, risk evaluation and risk control, and these elements shall be carried out according to GB/T 42062-2022.

5.6 Incorrect connection of the parts of an active implantable medical device: where incorrect connection would bring an unacceptable risk, the design and construction of the active implantable medical device shall prevent incorrect connection unless this is impracticable; where it is impracticable, suitable marking, warnings and instructions shall be provided. Conformity is confirmed by examining the risk assessment and, where necessary, by inspecting the marking, the warnings and the instructions.