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

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**General specifications for medical foot switch
(English Translation)**

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1 Scope

This Standard specifies the terms and definitions, requirements and test methods for medical foot switches.

This Standard applies to foot switches used as control circuit components for medical electrical equipment. The scope of application of this Standard does not include pneumatic and hydraulic foot switches.

NOTE: Foot switches that are not within the scope of application of this Standard can still refer to the relevant provisions of this Standard.

2 Normative references

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

GB 4208-2008 Degree of protection provided by enclosure (IP code) GB 9706.1 Medical electrical equipment - Part 1: General requirements for safety

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

make-contact element (normally open) A contact element that closes a circuit when the switch is activated.

break-contact element (normally closed) A contact element that breaks a circuit when the switch is activated.

4.1.1 Starting force

The starting force of the foot switch shall be no less than 10 N and no more than 50 N.

4.1.2 Working resistance

For a foot switch that uses a make-contact element (normally open)/break-contact element (normally closed), when the contact element is closed, the working resistance shall not be greater than 500 mohm.

4.1.3 Mechanical strength

4.1.3.1

The foot switch shall be able to withstand the weight of an adult in the normal position.

4.1.3.2

The foot switch shall not be significantly damaged after an accidental fall.

4.1.3.3 After completing the mechanical strength test, the foot switch shall still meet

the requirements of 4.1.1 and keep the expected function intact.

4.1.3.4 After completing the mechanical strength test, the control setting of the foot

switch shall not change when it is in an abnormal use position.

Example. When a foot switch that uses a make-contact element (normally open) is placed upside down relative to the normal use position, its contact element will not close.

4.1.4 Mechanical durability

4.1.4.1

The foot switch shall have sufficient mechanical durability.

4.1.4.2 After completing the mechanical durability test, the foot switch that uses a

make-contact element (normally open)/break-contact element (normally closed) shall still meet the requirements of 4.1.2.

4.1.4.3 After completing the mechanical durability test, the foot switch shall still meet

the requirements of 4.1.1 and keep the expected function intact.

4.1.4.4 After completing the mechanical durability test, the control setting of the foot

switch shall not change when it is in an abnormal use position.

4.1.5 Bending test of connecting wires

After the test specified in 5.1.5, the port connector of the foot switch connecting wire shall not be damaged and the expected function shall be intact.

4.1.6 Liquid ingress

After completing the tests of 5.1.3, 5.1.4 and 5.1.6, the foot switch shall be tested for water ingress as specified in Clause 14 of GB 4208-2008 according to the liquid ingress