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

YY 0780-2025

Replacing YY 0780-2018

**Traditional Chinese medical device - Electroacupuncture
therapy device**

中医器械 电针治疗仪

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting. This document replaces YY 0780-2018 "Electroacupuncture Therapy Instrument". Compared with YY 0780-2018, the only changes are structural adjustments and editorial modifications. In addition, the main technological changes are as follows:

---The requirements and test methods for output short-circuit and open-circuit protection have been changed (see 4.7, 5.7, and

5.7 in the 2018 version);

---The requirements and test methods for the biocompatibility of electrode needles have been removed (see

5.8.2 in the 2018 version);

---The requirements and test methods for electrode pin connectors and electrode wires have been changed (see 4.9, 5.9, and

5.9 in the 2018 edition);

---The requirements for external markings on the device have been changed (see 4.10.2.1, version

4.10.2.1 of 2018);

---Electromagnetic compatibility requirements and test methods have been removed (see

5.11 in the 2018 edition);

---The test method for the DC component has been changed (see 5.2.2, 2018 version 5.2.2);

---The test method for pulse energy has been changed (see 5.2.3,

1 Scope

YY 0780 is the mandatory standard for the electroacupuncture therapy device, the stimulator that drives current through acupuncture needles. It specifies the requirements for electroacupuncture instruments and describes the corresponding test methods, and it applies to instruments used for treatment and adjunctive therapy by electrical stimulation through needles. The YY prefix without /T makes compliance compulsory in China, which is unusual for a traditional medicine device and reflects the fact that current delivered through a needle into tissue is an electrical safety question before it is a therapeutic one: output waveform, current limits and fault behaviour are what the standard controls. The 2025 edition takes effect on 1 July 2028. For a manufacturer or an exporter of electroacupuncture units, this is the governing standard.

This document specifies the requirements for electroacupuncture therapy devices (hereinafter referred to as "therapeutic devices") and describes the corresponding test methods. This document applies to instruments that provide treatment and adjunctive therapy to patients via electroacupuncture.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 2024 Acupuncture Needles

GB 9706.1 Medical electrical equipment - Part

3 Terms and Definitions

The terms and definitions defined in YY 9706.210-2021, as well as the following terms and definitions, apply to this document.

3.1 An instrument that uses electroacupuncture to treat and assist patients.

Note. This typically includes the main unit, electrode wires, and electrode pin connectors, as well as the matching electrode pins.

3.2 Electroacupuncture After the needle is inserted into the muscle tissue to obtain the needling sensation, a small current is passed through the needle. This dual stimulation of needling and electricity is used as an adjunct therapy for diseases. method.

3.3 The acupuncture needles used in electroacupuncture therapy devices are connected to the electrode needle connector to conduct the current output by the therapy device to the muscle tissue.

3.4 Devices for connecting electrode wires to electrode needles include, but are not limited to, clip-on types.

3.5 Connect the electrode needle connector to the wires at the output terminals to transmit the output current of the therapeutic device.

Note. It consists of multiple sections, including adapters.