

ICS 11.040.60
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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0950-2015

**Extracorporeal pressure wave therapy devices by compressed
air**

(English Translation)

Issued on: March 2, 2015

Implemented on: January 1, 2017

Issued by: State Food and Drug Administration

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Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

The safety requirements of this standard fully implement the requirements of GB 9706.1-2007 "Medical Electrical Equipment Part 1: General Safety Requirements" content:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by China Food and Drug Administration:

This standard is under the jurisdiction of the Physical Therapy Equipment Sub-Technical Committee (SAC/TC10/SC4) of the National Medical Electrical Appliances Standardization Technical Committee:

This standard was drafted: State Food and Drug Administration Tianjin Medical Device Quality Supervision and Inspection Center:

1 Scope

This standard specifies the terms and definitions, composition, requirements, and test methods of pneumatic ballistic extracorporeal pressure wave therapy equipment (hereinafter referred to as equipment):

Laws, inspection rules, signs, instructions for use, packaging, transportation and storage:

This standard applies to the equipment specified in 3:1:

This standard does not apply to pneumatic ballistic lithotripsy equipment:

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document pieces: For undated references, the latest version (including all amendments) applies to this document:

GB/T 191-2008 Packaging, storage and transportation icon marks GB 9706.1-2007 Medical Electrical Equipment Part 1: General Safety Requirements GB/T 14710-2009 Environmental requirements and test methods for medical electrical appliances GB/T 16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process GB/T 16886.5 Biological evaluation of medical devices - Part 5: In vitro cytotoxicity test GB/T 16886.10 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed hypersensitivity YY/T 0149-2006 Test method for corrosion resistance of medical stainless steel YY/T 0466.1-2009 Symbols for medical device labeling, marking and providing information for medical devices Part 1: General Require

3 Terms and Definitions

The following terms and definitions defined in GB 9706.1-2007 apply to this document:

The energy generated by compressed air is used to drive the bullet body in the treatment handle, so that the bullet body pulses to impact the treatment head, and the elasticity of the two is used:

The impact generates pressure waves, which are transmitted percutaneously to the device for the treatment of painful parts:

control handle the operator holds the device and controls the compressed air to drive the projectile body to collide with the treatment head to generate pressure waves:

bullet body projectile Located in the cavity of the control handle, it is a rigid body that elastically collides with the treatment head under the drive of compressed air:

energy converterenergytransmitter treatment head Located at the end of the control handle, the part that is in contact with the patient: Generally, it is a rigid material, and after elastic collision with the bullet body, the energy is transferred to YY 0950-2015