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

YY/T 0936-2014

Particular specifications for urology X-ray equipment

泌尿X射线机专用技术条件

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. Please note that some of the content of this document may involve patents. Distribution of this document Institutions do not assume the responsibility to identify these patents. This standard was proposed by the China Food and Drug Administration. This standard by the National Standardization Technical Committee on Medical Electrical medical X-ray equipment and utensils Standardization Technical Committee (SAC/TC10 / SC1) centralized. This standard was drafted. Siemens Shanghai Medical Equipment Co., Ltd., Liaoning Medical Device Control, Shenzhen Kang Hui Medical Devices have Limited. The main drafters of this standard. Liucong Zhi, Gao Chun Yu, Sun Zhaoan, Zhang Yong, Chen Ming, Chen Yansheng. Urinary tract X-ray machine for the technical conditions

1 Scope

YY/T 0936 is the particular specification for urological X-ray equipment, the fluoroscopy and radiography system built around a urology table for procedures such as lithotripsy guidance, retrograde studies and stent placement. It differs from a general radiographic room in the geometry it has to provide, the access it has to leave around a patient in the lithotomy position, and the fluoroscopy times these procedures involve, which makes dose management a defining requirement rather than a secondary one. The standard sets those particular requirements and the corresponding test methods on top of the general X-ray equipment standards. For a manufacturer or an importer of urology imaging systems for the Chinese market, this is the standard the type test is run against.

This standard specifies the urinary tract X-ray machine (referred to as the urinary machine) terms and definitions, classification and composition requirements and test methods. This standard applies to the manufacturer's declaration dedicated to diagnostic imaging and minimally invasive surgery of the urinary system of X-ray equipment.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references,

the latest edition (including any amendments) applies to this document.

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety

GB 9706.3-2000 Medical electrical equipment - Part 2. High-voltage generator safety device requirements for diagnostic X-ray generator

GB 9706.11-1997 Medical electrical equipment - Part II. diagnostic X-ray source assemblies and X-ray tube assemblies Claim

GB 9706.12-1997 Medical electrical equipment Part 1. General requirements for safety Collateral standard diagnostic X-ray radiation device. General requirements for emission protection

GB 9706.14-1997 Medical electrical equipment - Part 2. Safety ancillary equipment requirements for X-ray equipment

GB 9706.15-2008 Medical electrical equipment - Part 1-1. General requirements for safety Collateral standard medical electrical systems security Claim

GB/T 10149-1988 X-ray equipment for medical terminology and symbols

GB/T 10151-2008 medical diagnostic X-ray equipment voltage cable plug and socket

YY 0076-1992 metal parts coating technology classification conditions

YY/T 0106-2008 medical diagnostic X-ray machine general technical conditions

YY/T 0291-2007 medical X-ray equipment environmental requirements and test methods

YY 0505-2012 Medical electrical equipment - Part 1-2. General requirements for safety Collateral standard. Electromagnetic compatibility requirements and tests

YY/T 0708-2009 Medical electrical equipment - Part 1-4. General requirements for safety Collateral Standard. Programmable Electrical Medical Systems

3 Terms and Definitions

GB/T 10149-1988 define the following terms and definitions apply to this document.

3.1 Imaging time *imagingtime* Starting from generating X-rays on the screen shows the time required for a normal image.

3.2 Image brightness stability *stabilizationofimagebrightness* Refers to the different attenuation phantom case, the image brightness constant automatic control.

3.3 Perspective recovery time *fluoroscopyrecoverytime* After the device is powered down in perspective, the system can be re-energized to operate the perspective of time.