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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 18268.26-2010

**Electrical equipment for measurement, control and laboratory
use -- EMC requirements -- Part 26: Particular requirements -- In
vitro diagnostic (IVD) medical equipment**

测量、控制和实验室用的电设备 电磁兼容性要求

(English Translation)

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Table of Contents

Foreword	3
1 Scope	5
2 Normative references	5
3 Terms and definitions	6
4 General	6
5 EMC test plan	7
6 Immunity requirements	8
7 Emission requirements	10
8 Test results and test report	10
9 Instructions for use	10
Bibliography	12

1 Scope

The scope of GB/T 18268.1 applies to this Part. In addition, this Part of GB/T

18268 specifies minimum requirements for immunity and emissions regarding electromagnetic compatibility for in vitro diagnostic medical equipment, considering the particularities and specific aspects of this electrical equipment and their electromagnetic environment.

2 Normative references

The following documents contain the provisions which, through reference in this

Part of GB/T 18268, become the provisions of this Part. For dated references, their subsequent amendments (excluding corrigendum) or revisions do not apply to this Part. However, the parties who enter into agreement based on this

Standard are encouraged to investigate whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Part.

GB/T 4365-2003 Electrotechnical terminology - Electromagnetic compatibility (IEC 60050-161:1990, IDT)

GB 4824 Industrial, scientific and medical (ISM) radio-frequency equipment

- Electromagnetic disturbance characteristics - Limits and methods of measurement (GB 4824-2004, CISPR 11:2003, IDT)

GB/T 17626.2 Electromagnetic compatibility (EMC) - Testing and measurement techniques - Electrostatic discharge immunity test (GB/T

17626.2-2006, IEC 61000-4-2:2001, IDT)

GB/T 17626.3 Electromagnetic compatibility - Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test (GB/T 17626.3-2006, IEC 61000-4-3:2002, IDT)

GB/T 17626.4 Electromagnetic compatibility - Testing and measurement techniques - Electrical fast transient/burst immunity test (GB/T 17626.4-2008,

IEC 61000-4-4:2004, IDT)

GB/T 17626.5 Electromagnetic compatibility - Testing and measurement techniques - Surge immunity test (GB/T 17626.5-2008, IEC 61000-4-5:2005,

IDT)

GB/T 17626.6 Electromagnetic compatibility - Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields (GB/T 17626.6-2008, IEC 61000-4-6:2006, IDT)

GB/T 17626.8 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test (GB/T 17626.8-2006, IEC 61000-4-8:2001, IDT)

GB/T 17626.11 Electromagnetic compatibility - Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests (GB/T 17626.11-2008, IEC 61000-4-11:2004, IDT)

GB/T 18268.1-2010 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (IEC

61326-1:2005, IDT)

ISO 14971:2000 Medical devices - application of risk management to medical devices

3 Terms and definitions

For the purposes of this Part, the terms and definitions given in GB/T 18268.1 and GB/T 4365 as well as the following apply.

3.1

in vitro diagnostic medical equipment

Instruments and apparatus intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease. Such instruments or apparatus are intended for use in the collection, preparation,

and examination of specimens taken from the human body.

4 General

Clause 4 of GB/T 18268.1 applies to this Part, with the following addition.