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Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Endoscopic Equipment

医用电气设备 第 2 部分：内窥镜设备安全专用要求

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Table of Contents

Foreword

This Standard equivalently adopts IEC 60601-2-18:1996 *Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Endoscopic Equipment*.

This Standard is used in conjunction with international standard IEC 60601-1 *Medical Electrical Equipment – Part 1: General Requirements for Safety*, which has been transferred into national standard GB 9706.1-1995. IEC 60601-1-1 *Medical Electrical Equipment – Part 1: General Requirements for Safety* has been approved.

Annex L of this Standard is for reference.

Annex AA of this Standard is informative.

This Standard was proposed by National Medical Products Administration.

This Standard shall be under the jurisdiction of National Technical Subcommittee on Medical Optics and Instrument of Standardization Administration of China.

Drafting organization of this Standard: Hangzhou Center for Medical Device Quality Supervision and Testing of National Medical Products Administration.

Chief drafting staffs of this Standard: He Tao, Wen Yan, and Zhen Hui.

Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Endoscopic Equipment

This Particular Standard equivalently adopts IEC 60601-2-18:1996 *Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Endoscopic Equipment*; and shall be used in conjunction with GB 9706.1-1995 *Medical Electrical Equipment - Part 1: General Requirements for Safety*.

SECTION ONE – GENERAL

This Clause of and classification clause of the General Standard apply, except as follows:

1 Scope and Object

This clause of the General Standard applies, except as follows:

1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety of ENDOSCOPIC EQUIPMENT and its INTERCONNECTION CONDITIONS with ENDOSCOPICALLY-USED ACCESSORIES.

NOTE - As the General Standard does not give requirements for the safety of APPLIED PARTS of different MEDICAL ELECTRICAL EQUIPMENT when used together, this standard gives requirements for specific INTERCONNECTION CONDITIONS commonly encountered during the Use Of ENDOSCOPES.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ENDOSCOPIC EQUIPMENT and enable parts Of ENDOSCOPIC EQUIPMENT to be tested together or individually.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as “General Standard”, consisting of GB 9706.1-1995 *Medical electrical equipment - Part 1: General requirements for safety*; IEC 60601-1:1998*Medical electrical equipment - Part 1: General requirements for safety, amendment 2*; IEC 60601-1-1:1992 *Medical electrical equipment - Part 1: General requirements for safety, 1: Collateral Standard: Safety requirements for medical electrical systems, amendment 1*; and IEC 60601-1-2: 1993 *Medical electrical equipment - Part I : General requirements for safety, 2: Collateral standard: Electromagnetic compatibility - Requirements and tests*.

GB 9706.1-1995 and IEC 60601-1:1998 Amendment 2 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”; and IEC 60601-1-1:1992 and IEC 60601-1-2:1993 as the “Collateral Standards”.

The term “this Standard” covers this Particular Standard, used together with the General Standard and Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause of subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative annex AA. Annex AA is not part of this Particular Standard and only gives additional information; it can never be the subject of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standards, although possibly irrelevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General

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