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

GB 9706.4-2009

**Medical electrical equipment -- Part 2-2: Particular requirements
for the safety of high frequency surgical equipment
(English Translation)**

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Foreword

All technical contents of this Part are mandatory.

Medical electrical equipment standards are a series of standards, consisting of two major parts.

- Part 1.General requirements for safety of medical electrical equipment;
- Part 2.Particular requirements for safety of medical electrical equipment.

This Part is "Particular requirements for the safety of high frequency surgical equipment" of Part 2 of "Medical electrical equipment". This Part shall be used in conjunction with the national standard GB 9706.1-2007 "Medical electrical equipment - Part 1.General requirements for safety". The requirements in this Part apply taking precedence over the corresponding clauses of GB 9706.1-2007.

This Part equivalently adopts the International Standard IEC 60601-2-2.2006 "Medical electrical equipment - Part 2-2.Particular requirements for the safety of high frequency surgical equipment".

In order to facilitate the use, IEC 60601-2-2.2006 has made the following editorial modifications.

- For the other International standards referenced in the standard, if the standard has been transformed into China's national standard, the number of referenced International standard is changed to the number of corresponding national standard;
- DELETE the cover and foreword of IEC 60601-2-2:2006.

This Part replaces GB 9706.4-1999 "Medical electrical equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment".

The main differences between this Part and GB 9706.4-1999 are as follows.

- ADD and SUPPLEMENT the content of terms and definitions;
- ADD the specification requirements for rated accessories voltage and monitoring neutral electrode in instructions for use;
- ADD the requirements for lateral coupling between different high frequency patient circuits in high frequency leakage current;
- ADD the requirements for incorrect output of high frequency surgical equipment under single fault condition;
- REARRANGE and SUPPLEMENT the content of 56.11;
- REPLACE Clause 101 in the original standard BY Clause 59, and add a larger length of content and requirements.

Appendix L, Annex AA and Annex BB of this Part are informative.

This Part is proposed by State Food and Drug Administration.

This Part is under the jurisdiction of Technical Sub-Committee on Medical Electrical Equipment of National Technical Committee on Medical Electrical Equipment of Standardization Administration of China.

Drafting organizations of this Part. Shanghai Medical Devices Testing Institute, Shanghai Hutong Electronics Co., Ltd.

Main drafters of this Part. Xu Yumin, Lu E, Shen Jiren.

The previous edition of the standards replaced by this Part are as follows.

- GB 9706.4-1992, GB 9706.4-1999.

1 Scope and object

This clause of the General Standard applies except as follows.

A requirement of this Particular Standard, replacing or modifying requirements of the General Standard or Collateral Standards, takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows.

Dimensionless value equal to the peak output voltage divided by the r.m.s. voltage as measured at the output of HF SURGICAL EQUIPMENT in an open circuit condition.

3 General requirements

This clause of the General Standard applies except as follows.

Additional single fault conditions.

4 General requirements for tests

This clause of the General Standard applies except as follows.

5 Classification

This clause of the General Standard applies except as follows.

Amendment.

6 Identification, marking and documents

This clause of the General Standard applies except as follows.

Where certain functions are indicated by lights, these indicator lights shall have the following colours.

7 Power input

This clause of the General Standard applies except as follows.

The clauses and subclauses of this section of the General Standard apply except as follows.

14 Requirements related to classification

This clause of the General Standard applies except as follows.

The APPLIED PARTS of HF SURGICAL EQUIPMENT shall be TYPE BF or CF
APPLIED PARTS.

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