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Heat exchanger for heart-lung bypass

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Contents

Page

Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 1704** : 2008), which has been technically revised.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, published patent application or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, published patent application or utility model rights.

Heat exchanger for heart-lung bypass

Introduction

This Japanese Industrial Standard has been prepared based on ISO 7199 : 2016, Edition 3, and its Amendment 1 : 2020 with some modifications of the technical contents to reflect the local conditions in Japan. The amendment to the said International Standard has been incorporated into this Standard.

The vertical lines on both sides and dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies requirements for sterile, single-use, extracorporeal (i.e. for heart-lung bypass) heat exchangers intended for heat exchange of blood or myocardial protection fluid (hereafter referred to as heat exchangers). This Standard does not apply to

— implanted oxygenators (vascular intima oxygenators),

— extracorporeal blood-gas exchangers (oxygenators),

— liquid oxygenators,

— extracorporeal circuits (blood tubing), and

— separate ancillary devices.

NOTE The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 7199 : 2016 *Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)*+Amendment 1 : 2020 (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

The previous edition of this Standard, JIS T 1704 : 2008, remains valid for three years from the date of public notice of the revision of this Standard.

2 Normative references

Part or all of the provisions of the following standards, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS T 0993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*