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Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags

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Mita Avanti, 3-11-28, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

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 3231** : 2011), 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.

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Introduction

This Japanese Industrial Standard has been prepared based on ISO 15674 : 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 hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags intended for use as a blood reservoir during cardiopulmonary bypass (CPB) surgery (hereafter referred to as the reservoirs).

This Standard applies only to the blood reservoir aspects for multifunctional systems which can have integral parts such as blood-gas exchangers (oxygenators), blood filters, defoamers, blood pumps, etc.

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

ISO 15674 : 2016 *Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags* + 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 3231 : 2011, 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*

NOTE Normative reference in the corresponding International Standard: ISO