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Oxygenators

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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 3230** : 2008), which has been technically revised.

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Oxygenators

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 (heart-lung bypass) blood-gas exchangers intended for supply of oxygen to, and removal of carbon dioxide from, the blood of humans (hereafter referred to as oxygenators). This Standard also applies to heat exchangers and arterial filters that are integral parts of the oxygenator, and to external equipment unique to the use of the oxygenator. This Standard does not apply to

- implanted oxygenators (vascular intima oxygenators),
- liquid oxygenators,
- extracorporeal circuits (blood tubing),
- separate heat exchangers (single-use heat exchangers for heart-lung bypass),
- separate ancillary devices, and
- separate arterial line filters (single-use arterial filters for heart-lung bypass systems).

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**.

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.