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(MTJAPAN/JSA)

Urethral catheters

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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 3214** : 2011), which has been technically revised.

However, **JIS T 3214** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

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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Urethral catheters

Introduction

This Japanese Industrial Standard has been prepared based on ISO 20696 : 2018, Edition 1, with some modifications of the technical contents in order to reflect the actual situation in Japan.

The 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 urethral catheters, with or without a balloon, which are used for urethral catheterization, pressure hemostasis, cleaning of bladder, etc. (hereafter referred to as catheters). This Standard does not apply to nephrostomy catheters and cystostomy catheters to be placed through a stoma covered by ISO 20697.

NOTE 1 Requirements for ureteral stents are specified in JIS T 3270.

NOTE 2 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 20696 : 2018 *Sterile urethral catheters for single use* (MOD)

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

2 Normative references

The following standards contain provisions which, 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 0307 *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

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

NOTE Corresponding International Standard : ISO 10993-1 *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process*

3 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.

3.1