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(MTJAPAN/JSA)

**Catheters and tubes designed for the
biliary tract**

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In the event of any doubts arising as to the contents,
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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 3243** : 2017), which has been technically revised.

However, **JIS T 3243** : 2017 remains valid for three years from the date of public notice of the revision of this Standard.

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Catheters and tubes designed for the biliary tract

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 20697** : 2018, Edition 1, with some modifications of the technical contents to reflect the conditions unique to 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 tubes and catheters designed for the biliary tract, and their accessory devices. They are inserted into biliary tract [biliary duct (intrahepatic biliary duct, extrahepatic biliary duct), cholecyst, cystic duct, and papilla] or pancreatic duct, in the transduodenal, percutaneous transhepatic, or open abdominal surgery, for the purposes of performing treatments such as pus discharge, drainage, perfusion, expansion of stricture parts or papilla, prevention of stricture, fragmentation, grasp and collection, extraction and purge of calculus.

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

ISO 20697 : 2018 *Sterile drainage catheters and accessory devices for single use* (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

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 0601-2-18 *Medical electrical equipment — Part 2-18 : Particular requirements for the basic safety and essential performance of endoscopic equipment*

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*