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**Drainage catheters and accessory
devices**

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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 3215** : 2011), which has been technically revised.

However, **JIS T 3215** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

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Drainage catheters and accessory devices

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 20697** : 2018, Edition 1, with some modifications of the technical contents in order to reflect the actual situation in Japan.

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 drainage catheters and their accessory devices, where the catheter is placed in a body cavity or wound, surgically or percutaneously, for drainage of accumulated fluid or air to the exterior. This Standard is not applicable to those with a special shape at the tip (pigtail, balloon, etc.) to maintain placement in the body, or to the following :

- suction catheters used by airway;
- tracheal catheters (tracheal tube);
- urethral catheter;
- ureteral stents, biliary stents, and other stents;
- drainage catheters placed in digestive tracts percutaneously with gastrostomy technique;
- neuraxial catheters used for removal of cerebrospinal fluid;
- enteral catheters used for removal of solutions or substances from the gastrointestinal tract;
- catheters for nephrostomy or cystostomy;
- catheters and tubes designed for the biliary tract.

NOTE The International Standards 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 Standards and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.