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**Catheters for drainage use in the
stomach and esophagus**

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Catheters for drainage use in the stomach and esophagus

1 Scope This Japanese Industrial Standard specifies requirements for sterile or unsterilized catheters for drainage use in the stomach and esophagus (hereafter referred to as “catheters”), which are designed to be nasogastrically or orally inserted into and be left in the stomach and esophagus for the purpose of aspiration, drainage, evacuation, cleaning and removal of foreign objects, etc.

This Standard does not include requirements for X-ray permeability of catheters.

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions (including amendments) of the standards 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*

ISO 594-1 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 1: General requirements*

3 Terms and definitions For the purposes of this Standard, the following definitions apply.

- a) **catheters for drainage use in the stomach and esophagus** medical device which is composed of flexible tube and designed so that it can be nasogastrically or orally inserted into and left in the stomach and esophagus for the purpose of aspiration, drainage, evacuation, cleaning and removal of foreign objects, etc.
- b) **tip part** tip of catheters to be inserted into the body
- c) **part at hand** part of catheters for connecting with other connectors, at the opposite end of the tip part
- d) **tip opening** opening in the centre of the tip part
- e) **side hole** opening in the side face around the tip part
- f) **shaft** body of catheters to be inserted into the body

4 Configuration and name of each part Configuration and name of each part of the typical catheter are illustrated in figure 1, whose tip part and part at hand are as follows. However, illustration in figure 1 is only an example of configuration and name of each part of the typical catheter.

- a) **Tip part** Tip part shall be provided with tip opening or one or more side hole(s).
- b) **Part at hand** Part at hand shall be as follows.