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**Enteral feeding catheters and enteral
giving sets**

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Foreword

This translation has been made based on the original Japanese Industrial Standard 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 Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 3213 : 2005** is replaced with this Standard.

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Enteral feeding catheters and enteral giving sets

Introduction

This Japanese Industrial Standard is the Standard which is revised so that the contents such as terms and, constitution of documents are altered for the convenience of users in the reviewing of **JIS T 3213** established in 2005.

1 Scope

This Standard specifies the sterilized or unsterilized enteral giving sets and enteral feeding catheters for the purpose of nutritional administration or decompression. Furthermore, this Standard specifies the design and test method of the joint mechanism.

However, this Standard does not include the requirements for X-ray impermeability of enteral feeding catheters.

Moreover, **JIS T 3213 : 2005** may be applied until July 28th, 2014.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the edition of the indicated year shall apply and the revisions (including amendments) made thereafter shall not apply.

JIS T 0307 : 2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

JIS T 0993-1 : 2005 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

3 Terms and definitions

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

3.1 enteral giving set

medical device leading nutritional supplements or dietetic foods into an enteral feeding catheter from the container, whose joint part with the enteral feeding catheter is of a connector for prevention against incorrect connection (see figure 1)

NOTE : A connector for prevention against incorrect connection shall have a form described in 4.1.2, and not a form with 6 % (Lure) taper described in **ISO 594-1** and **JIS T 3201**.

3.2 enteral feeding catheter

medical device which consists of flexible tube and connecting part with one or more small hole(s), and which is designed so that nutritional supplements, foods and drinks are administered into stomach or intestine

There are also types of catheters with a weight or an olive shaped ball for easy insertion of the catheter on the tip or near the tip of the catheter.