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(MTJAPAN/JSA)

**Enteral feeding catheters and  
enteral giving sets**

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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 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**:2011 is replaced with this Standard.

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# Enteral feeding catheters and enteral giving sets

## Introduction

This Japanese Industrial Standard was established in 2005 and has gone through the revision made in 2011 up to the present. Since **ISO 80369-3** has been established in relation to connectors specified in this Standard, this Standard has been revised to add the standard to normative references.

## 1 Scope

This Standard specifies the sterilized or unsterilized enteral giving sets and enteral feeding catheters for the purpose of nutritional administration or decompression. This Standard also specifies the design and test methods of the connectors.

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

NOTE **JIS T 3213:2011** may be applied until April 30, 2021.

## 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 editions of the indicated year shall be applied and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent edition (including amendments) shall be applied.

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

JIS T 0993-1:2012 *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*

ISO 80369-3:2016 *Small-bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications*

## 3 Terms and definitions

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

### 3.1

#### enteral giving set

medical device for leading nutritional supplements or dietetic foods into an enteral feeding catheter from the container

The joint part between the enteral giving set and the enteral feeding catheter has a connector for preventing misconnections (see Figure 1).

NOTE A connector for preventing misconnection is as specified in **ISO 80369-3** and in the shape given in Figure 2 but not in the shape of 6 % (Lure) taper specified in **ISO 80369-7** or **JIS T 3201**.