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Drainage catheters and accessory devices

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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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Drainage catheters and accessory devices

1 Scope This Japanese Industrial Standard specifies the requirements for drainage catheters and accessory devices (drainage catheters, drainage system and their accessories), which are designed to evacuate liquid or gas from the body by gravitation or with negative pressure. However, this Standard does not apply to the following:

- Catheters for suction used by airway
- Catheters for trachea (tracheal tube)
- Catheters for nephrostomy or cystostomy
- Catheters for urinary passage

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. If the indication of the year of coming into effect is given to these referred standards, only the edition of indicated year constitutes the provision of this Standard but the revision and amendment made thereafter do not apply. The normative references without the indication of the year of coming into effect apply only to the most recent edition (including amendments).

JIS T 0307:2004 *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*

3 Definitions For the purposes of this Standard, the following definitions apply:

3.1 drainage catheter tubes and catheters designed for collection of liquid or gas, or for percutaneous or surgical insertion into cavitas thoracis, abdominal cavity, wound part, etc. of short term or of long term

3.2 collecting tools tools which are designed to collect liquid or gas in bags which are a part of the drainage system, bellows, bottles and other vessels, and which are connected with the drainage catheter directly or through connecting tube

3.3 drainage system drainage catheters and/or collecting tools, and accessory devices such as source of suction, connecting tube, connector and trocar, if applicable

Remarks 1 The drainage system has two types : one can be used as it is, and the other may be used with some parts assembled by the user.

- 2 The drainage can be done by gravitation, negative pressure produced by external power supply, operation by a user, or prior discharge of the collecting tools.

3.4 connecting tube tubes designed to assemble accessories of the drainage system

3.5 trocar needles, tapered rods, sleeves or a combination of these, which assist in inserting the drainage catheter into body tissue or body cavity

3.6 source of suction self-support typed tools which can apply negative pressure on drainage catheters or system

Remarks : Source of suction may be collecting tools.

4 Requirements

4.1 Resistance to deflection The drainage system or its accessories intended to suck by applying negative pressure, when tested according to Annex A, shall not show deflection such as may damage the function of tools. The maximum negative pressure shall be the suction pressure at the initiation of suction as specified by the relevant manufacturer.

4.2 Stress at breakage

4.2.1 Connecting part The minimum force applied on connecting parts at breakage, when the parts are tested according to Annex C, shall be as shown in table 1.

Table 1 Minimum force applied on connecting parts at breakage

Nominal outside diameter mm	Minimum force at breakage N
2 >	5
2 to 4	5
> 4	15

4.2.2 All other accessories of drainage catheters and system The minimum force applied on connecting parts at breakage, when the parts are tested according to Annex D, shall be as shown in table 2.

Table 2 Minimum force applied on all other accessories of drainage catheters and system at breakage

Nominal outside diameter mm	Minimum force at breakage N
2 >	5
2 to 4	10
> 4	20