

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 1553 : 2023

(JMOIA/JSA)

**Optics and optical instruments — Medical
endoscopes and endotherapy devices**

ICS 11.040.55

Reference number : JIS T 1553 : 2023 (E)

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T 1553 : 2023

Date of Establishment: 1984-11-15

Date of Revision: 2023-05-25

Date of Public Notice in Official Gazette: 2023-05-25

Investigated by: Japanese Industrial Standards Committee

Standards Board for ISO area

Technical Committee on Medical Equipment

JIS T 1553 : 2023, First English edition published in 2024-06

Translated and published by: Japanese Standards Association
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In the event of any doubts arising as to the contents,
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Contents

| | Page |
|--|------|
| Introduction | 1 |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 2 |
| 4 Requirements | 6 |
| 4.1 General | 6 |
| 4.2 Surface and edges | 6 |
| 4.3 Maximum insertion portion width | 6 |
| 4.4 Minimum instrument channel width | 6 |
| 4.5 Field of view | 7 |
| 4.6 Direction of view | 7 |
| 4.7 Safety | 7 |
| 4.8 Biological compatibility | 7 |
| 4.9 Fittings/connectors for liquid or gaseous media | 7 |
| 4.10 Deflection control system for the controllable portion | 7 |
| 4.11 Environmental requirements | 10 |
| 5 Testing | 10 |
| 5.1 General | 10 |
| 5.2 Surface and edges | 10 |
| 5.3 Maximum insertion portion width | 10 |
| 5.4 Minimum instrument channel width | 10 |
| 5.5 Field of view | 10 |
| 5.6 Direction of view | 10 |
| 6 Marking | 10 |
| 6.1 Minimum marking | 10 |
| 6.2 Marking legibility | 11 |
| 6.3 Marking exceptions | 11 |
| 7 Instruction manual | 11 |
| 8 Packaging | 12 |
| Annex A (informative) Guidelines on the application of risk management to endoscopic system connector | 13 |
| Annex B (normative) Determination of field of view and direction of view of endoscopes with optics | 16 |
| Annex C (normative) Determination of maximum width of insertion portion | 23 |

| | | |
|------------------------|---|----|
| Annex JA (informative) | Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment : General requirements | 26 |
| Annex JB (informative) | Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment : Lock fittings | 34 |
| Annex JC (informative) | Comparison table between JIS and corresponding International Standards | 46 |

Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Medical-Optical Equipment Industrial Association (JMOIA)/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 1553** : 2005), which has been technically revised.

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Optics and optical instruments — Medical endoscopes and endotherapy devices

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8600-1** : 2015 (Edition 4), **ISO 8600-3** : 2019 (Edition 2) and **ISO 8600-4** : 2014 (Edition 2) with some modifications of the technical contents.

Annex JA and Annex JB are unique to **JIS** and not given in the corresponding International Standards. The dotted underlines indicate changes from the corresponding International Standards. A list of modifications with the explanations is given in Annex JC.

1 Scope

This Standard gives requirements for endoscopes and endotherapy devices used in the practice of medicine.

NOTE The International Standards corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 8600-1 : 2015 *Endoscopes — Medical endoscopes and endotherapy devices — Part 1 : General requirements*

ISO 8600-3 : 2019 *Endoscopes — Medical endoscopes and endotherapy devices — Part 3 : Determination of field of view and direction of view of endoscopes with optics*

ISO 8600-4 : 2014 *Endoscopes — Medical endoscopes and endotherapy devices — Part 4 : Determination of maximum width of insertion portion* (Overall evaluation: MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

However, **JIS T 1553** : 2005 remains valid for three years from the date of public notice of the revision of this Standard.

2 Normative references

Part or all of the provisions of the following standards, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS T 0601-2-18 *Medical electrical equipment — Part 2-18 : Particular requirements for the basic safety and essential performance of endoscopic equipment*