



MALAYSIAN STANDARD

MS ISO 5361:2007

ANAESTHETIC AND RESPIRATORY EQUIPMENT – TRACHEAL TUBES AND CONNECTORS (ISO 5361:1999, IDT)

ISO 5361:1999 is endorsed as Malaysian Standard with the reference number MS ISO 5361:2007.

ICS: 11.040.10

Descriptors: metal equipment, anaesthetic equipment, tracheal tubes, fittings, plastic product, rubber products, specifications, dimensions, characteristics, crushing strength, packing, marking

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DEPARTMENT OF STANDARDS MALAYSIA

Committee representation

The Medical Devices Industry Standards Committee (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysian Medical Industries
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institut Penyelidikan Teknologi Nuklear Malaysia
Institute for Medical Research
Lembaga Perlesenan Tenaga Atom
Malaysian Medical Association
Malaysian Medical Devices Association
Malaysian Organization of Pharmaceutical Industry
Ministry of Health
Persatuan Pengguna-pengguna Standard Malaysia
Pharmaceutical Association of Malaysia
Radiation Physics, Biophysics and Medical Physics Sub-Group of Institute of Physics Malaysia
SIRIM QAS International Sdn Bhd (Product Certification Section)
Universiti Kebangsaan Malaysia (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

The Technical Committee on Disposable 'Single-use' Devices which recommends adoption of the ISO Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia
Association of Malaysian Medical Industries
Clinical Research Centre
Institute for Medical Research
Institute of Quality Malaysia
Malaysian Medical Association
Malaysian Medical Device Association
Malaysian Sterile Service Association
Ministry of Health
Pusat Perubatan Universiti Malaya
SIRIM Berhad (Secretariat)

NATIONAL FOREWORD

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Disposable “Single-use” Devices under the authority of the Medical Devices Industry Standards Committee.

This Malaysian Standard is identical with ISO 5361:1999, *Anaesthetic and respiratory equipment – Tracheal tubes and connectors*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

- a) In the source text, “this International Standard” should read as “this Malaysian Standard”
- b) the comma which is used as a decimal sign (if any), to read as a point;
- c) references to International Standards should be replaced by equivalent Malaysian Standards as follows:

<u>Referenced International Standard</u>	<u>Corresponding Malaysian Standard</u>
ISO 10993-1, <i>Biological evaluation of medical devices - Part 1: Guidance on selection of tests</i>	MS ISO 10933-1, <i>Biological evaluation of medical devices - Part 1: Guidance on selection of tests</i>

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

INTERNATIONAL
STANDARD

ISO
5361

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1999-09-15

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1999-12-15

**Anaesthetic and respiratory equipment —
Tracheal tubes and connectors**

Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéales et raccords



Reference number
ISO 5361:1999(E)

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Preview Only

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5361 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This first edition cancels and replaces previous editions of ISO 5361-1:1988, ISO 5361-2:1993, ISO 5361-3:1984, ISO 5361-5:1984 and ISO 7228:1993, which have been technically revised. The requirements of ISO 5361-4:1987, *Tracheal tubes — Part 4: Cole type*, have not been included in this revision because Cole type tubes are specialized tubes, and as such, are excluded from the scope of this International Standard.

Annexes A, B and C form a normative part of this International Standard.

Annex D is for information only.