MALAYSIAN STANDARD

MS ISO 5366-3:2007 (CONFIRMED:2013)

Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 3: Paediatric tracheostomy tubes (ISO 5366-3:2001, IDT)

ICS: 11.040.10

Descriptors: medical equipment, anaesthetic equipment, artificial breathing apparatus, tracheostomy tubes, plastic tubes, rubber tubes, specifications, dimensions, designation, design, tests, marking, packing, labeling

NOTE. This MS has been reviewed by the responsible committee and confirmed that its contents are current

DEPARTMENT OF STANDARDS MALAYSIA

DEVELOPMENT OF MALAYSIAN STANDARDS

The **Department of Standards Malaysia (STANDARDS MALAYSIA)** is the national standards and accreditation body of Malaysia.

The main function of STANDARDS MALAYSIA is to foster and promote standards, standardisation and accreditation as a means of advancing the national economy, promoting industrial efficiency and development, benefiting the health and safety of the public, protecting the consumers, facilitating domestic and international trade and furthering international cooperation in relation to standards and standardisation.

Malaysian Standards (MS) are developed through consensus by committees which comprise balanced representation of producers, users, consumers and others with relevant interests, as may be appropriate to the subject at hand. To the greatest extent possible, Malaysian Standards are aligned to or are adoption of international standards. Approval of a standard as a Malaysian Standard is governed by the Standards of Malaysia Act 1996 [Act 549]. Malaysian Standards are reviewed periodically. The use of Malaysian Standards is voluntary except in so far as they are made mandatory by regulatory authorities by means of regulations, local by-laws or any other similar ways.

For the purposes of Malaysian Standards, the following definitions apply:

Revision: A process where existing Malaysian Standard is reviewed and updated which resulted in the publication of a new edition of the Malaysian Standard.

Confirmed MS: A Malaysian Standard that has been reviewed by the responsible committee and confirmed that its contents are current.

Amendment: A process where a provision(s) of existing Malaysian Standard is altered. The changes are indicated in an amendment page which is incorporated into the existing Malaysian Standard. Amendments can be of technical and/or editorial nature.

Technical corrigendum: A corrected reprint of the current edition which is issued to correct either a technical error or ambiguity in a Malaysian Standard inadvertently introduced either in drafting or in printing and which could lead to incorrect or unsafe application of the publication.

NOTE: Technical corrigenda are not to correct errors which can be assumed to have no consequences in the application of the MS, for example minor printing errors.

STANDARDS MALAYSIA has appointed **SIRIM Berhad** as the agent to develop, distribute and sell Malaysian Standards.

For further information on Malaysian Standards, please contact:

Department of Standards Malaysia
Ministry of Science, Technology and Innovation
Level 1 & 2, Block 2300, Century Square
Jalan Usahawan
63000 Cyberjaya
Selangor Darul Ehsan
MALAYSIA

Tel: 60 3 8318 0002
Fax: 60 3 8319 3131
http://www.jsm.gov.my
E-mail: central@jsm.gov.my

OR

SIRIM Berhad
(Company No. 367474 - V)
1, Persiaran Dato' Menteri
Section 2, P. O. Box 7035
40700 Shah Alam
Selangor Darul Ehsan
MALAYSIA

Tel: 60 3 5544 6000
Fax: 60 3 5510 8095
http://www.sirim.my
E-mail: msonline@sirim.my

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Committee representation

The Industry Standards Committee on Medical Devices (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 Malaysia
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 Disposable 'Single-use' Devices which recommended the 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 Industry Standards Committee on Medical Devices.

This Malaysian Standard is identical with ISO 5366-3:2001, *Anaesthetic and respiratory equipment – Tracheostomy tubes – Part 3: Paediatric tracheostomy tubes*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

a) the comma which is used as a decimal sign (if any), to read as a point;

b) references to International Standards should be replaced by equivalent Malaysian Standards as follows:

Referenced International Standards	Corresponding Malaysian Standards
ISO 5361, *Anaesthetic and respiratory equipment - Tracheal tubes and connectors*	MS ISO 5361, *Anaesthetic and respiratory equipment - Tracheal tubes and connectors*
ISO 10993-1, *Biological evaluation of medical devices - Part 1: Guidance on selection of tests*	MS ISO 10933-1, *Biological evaluation of medical devices - Part 1: Guidance on selection of tests*

c) within the text of this standard, the words "this International Standard" have been replaced by "this Malaysian Standard".

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.

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 5366 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5366-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 5366-3:1994), which has been technically revised.

ISO 5366 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Tracheostomy tubes*:

— *Part 1: Tubes and connectors for use in adults*

— *Part 3: Paediatric tracheostomy tubes*

Annexes A and B form a normative part of this part of ISO 5366. Annex C is for information only.