



MALAYSIAN STANDARD

MS ISO 1135-4:2009

TRANSFUSION EQUIPMENT FOR MEDICAL USE - PART 4: TRANSFUSION SETS FOR SINGLE USE (FIRST REVISION) (ISO 1135-4:2004, IDT)

ISO 1135-4:2004 is endorsed as Malaysian Standard with the reference number MS ISO 1135-4:2009.

ICS: 11.040.20

Descriptors: transfusion equipment, single use medical device

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Committee representation

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

Association of Malaysian Medical Industries
Association of Private Hospitals of Malaysia
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Lembaga Perlesenan Tenaga Atom
Malaysia Medical Device Association
Malaysian Association of Standards Users
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Organization of Pharmaceutical Industry
Malaysian Rubber Board
Malaysian Rubber Export Promotion Council
Ministry of Health Malaysia
Pharmaceutical Association of Malaysia
Radiation Physics, Biophysics and Medical Physics Sub-Group of Institute of Physics Malaysia
SIRIM Berhad (Secretariat)
SIRIM QAS International Sdn Bhd
Universiti Kebangsaan Malaysia (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

The Technical Committee on 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 Quality Malaysia
Malaysia Medical Device Association
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Rubber Board
Malaysian Sterile Service Association
Ministry of Health Malaysia
Ministry of Health Malaysia (Medical Device Bureau)
SIRIM Berhad (Secretariat)

MS ISO 1135-4:2009

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 and Facilities for Healthcare.

This Malaysian Standard is the first revision of MS 1099, *Specification for single-use (sterile) infusion sets for general medical use*.

This Malaysian Standard is identical with ISO 1135-4:2004, *Transfusion equipment for medical use - Part 4: Transfusion sets for single use*, 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 "this Malaysian Standard";
and
- b) the comma which is used as a decimal sign (if any), to read as a point.

This Malaysian Standard cancels and replaces MS 1099:1987.

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, 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.

**Transfusion equipment for medical use —
Part 4:
Transfusion sets for single use**

Matériel de transfusion à usage médical —

Partie 4: Appareils de transfusion non réutilisables



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