



MALAYSIAN STANDARD

MS 1949:2007

STERILE DRAINAGE CATHETERS AND ACCESSORY DEVICES FOR SINGLE USE

ICS: 11.040.20

Descriptors: medical equipment, disposable equipment, catheters, definitions, mechanical strength, shock resistance, tests, labelling

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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 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 recommends adoption of the EN 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 Malaysia
Pusat Perubatan Universiti Malaya
SIRIM Berhad (Secretariat)

FOREWORD

The adoption of the EN 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 EN 1617:1997, *Sterile drainage catheters and accessory devices for single use*, published by the European Committee for Standardization (CEN) with the exceptions as listed below.

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MALAYSIAN STANDARD EXCEPTIONS

- a) in the source text, "this European Standard" should read "this Malaysian Standard";
- b) the comma which is used as a decimal sign (if any), to read as a point; and
- c) reference to an EN Standard should be replaced by an equivalent Malaysian Standard as follows:

Referenced EN Standard

Corresponding Malaysian Standard

EN 1618:1997, *Catheters other than intravascular catheters - Test methods for common properties*

MS 1950:2007, *Catheters other than intravascular catheters - Test methods for common properties*

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