MALAYSIAN STANDARD

MS 2299-1:2010
(CONFIRMED:2015)

Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

ICS: 13.340; 11.140

Descriptors: protective equipment, medical gloves for single use, hospital equipment

NOTE. This Malaysian Standard has been reviewed and confirmed as being current.

FOR SALE WITHIN MALAYSIA ONLY

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

CONTENTS

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 Malaysia Medical Industries
Atomic Energy Licensing Board
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
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
Ministry of Health Malaysia (Medical Device Bureau)
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
Universiti Teknologi Malaysia

The Technical Committee on Disposable Single Use Devices which recommended the adoption of the EN Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia
Association of Malaysia Medical Industries
Institute for Medical Research
Institute of Quality Malaysia
Malaysia Medical Device Association
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Rubber Board
Malaysian Sterile Service Association
Ministry of Health Malaysia (Medical Device Bureau)
Pusat Penyelidikan Klinikal (PPK)
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 Industry Standards Committee on Medical Devices and Facilities for Healthcare.

This Malaysian Standard is identical with EN 455-1:2000, *Medical gloves for single use - Part 1: Requirements and testing for freedom from holes*, published by the European Committee for Standardization (CEN). However, for the purposes of this Malaysian Standard, the following apply:

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 European Standard should be replaced by corresponding Malaysian Standard as follows:

Referenced EN Standards	Corresponding Malaysian Standards
ISO 2859-1, *Sampling procedures for inspection by attributes - Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by -lot inspection*	MS ISO 2859-1, *Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptable quality level (AQL) for lot-by -lot inspection*

This standard is published with the permission of the European Committee for Standardization. Such permission is hereby acknowledged.

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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-1

October 2000

ICS 13.340

Supersedes EN 455-1:1993

English version

Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

Gants médicaux non réutilisables - Partie 1: Détection des trous - Prescriptions et essais

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 1: Anforderungen und Prüfung auf Dichtheit

This European Standard was approved by CEN on 16 September 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 455-1:2000 E

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205, Non-active medical devices, the Secretariat of which is held by BSI.

This European Standard supersedes EN 455-1:1993

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard applies to medical gloves for single use and has been prepared in three parts. This part addresses freedom from holes; Part 2 addresses physical properties and Part 3 addresses requirements and testing for biological evaluation.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This part of this standard specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.

NOTE Attention is drawn to EN 374-1 "Protective gloves against chemicals and micro-organisms – Part 1: Terminology and performance requirements".

2 Normative Reference

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

ISO 2859-1, *Sampling procedures for inspection by attributes - Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*

3 Term and definition

For the purposes of this standard the following term and definition apply:

3.1
medical gloves for single use
gloves intended for use in the medical field to protect patient and user from cross-contamination

4 Requirement

Medical gloves for single use shall not leak when tested in accordance with clause 5.

5 Watertightness test for detection of holes

5.1 Referee testing

Vertically position a filling tube of dimensions shown in Figure 1 or of dimensions to fit the glove and such that the tube is capable of holding any of the 1 000 ml of water that may exceed the natural fill volume of the glove.

Attach the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secure it by suitable means to obtain a watertight seal without damaging the glove (see Figure 1).

Add 1 000 ml ± 50 ml of water at a temperature of (15 to 35) °C into the open end of the filling tube, allowing the water to pass freely into the glove.

NOTE Some of the water may remain in the filling tube depending on the glove being tested.

Immediately inspect the glove visually for water leakage. Allow the glove to hang and visually inspect the glove for water leakage again after a period of 2 min to 3 min.

If, because of distension of the glove, the water does not rise to within 40 mm of the cuff end, raise the glove after the second inspection by a suitable means until the water level reaches 40 mm from the cuff end. Inspect visually the previously untested portion of the glove after a further period of 2 min to 3 min.

Disregard leakages within 40 mm of the cuff.

5.2 Routine testing

Routine testing shall be either by the watertightness test given in 5.1 or by another test which is validated against this test.

6 Sampling, inspection level and AQL

Each lot shall be sampled in accordance with ISO 2859-1 general inspection level 1, but utilizing a minimum sample size and corresponding acceptance/rejection numbers equivalent to sample size code letter L. When tested by the method described in 5.1 for referee purpose, the compliance level for freedom from holes shall be an AQL of 1,5.

NOTE This inspection level meets the requirements of Annex IV point 6.3 of the Medical Devices Directive, 93/42/EEC, and does not entail excessive sample sizes which would impact on manufacturing and testing costs. A minimum sample size equivalent to sample size code letter L is necessary to ensure that an adequate assessment of the quality of the lot is obtained when the lot size is small or unknown.

7 Test report

Any test report shall include at least the following information:

– a reference to this part of EN 455;

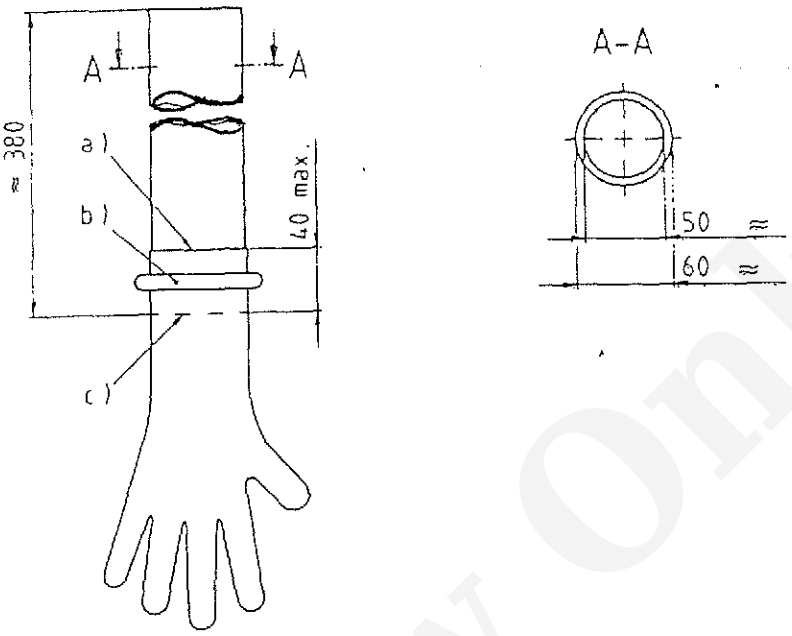
– the type of gloves and manufacturing batch code;

– the name and address of the manufacturer or distributor and test laboratory, if different;

– the date of the test performed;

– the test results (batch size, sample size, number of non-conforming gloves).

Dimensions in millimetres



Key

a) Cuff end of glove

b) Locking device

c) Fill tube overlapping

Figure 1 - Watertightness test - Filling tube

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European standard has been prepared under a mandate given to CEN/CENELEC by the European commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard, as detailed in table ZA.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 - Correspondence between this European Standard and EU Directives

Clause/sub-clause of this European Standard	Corresponding essential requirement of Directive 93/42/EEC	Comments
4	1, 2, 3, 7.2, 8.1	
5	1, 2, 3, 7.2	
5.2	8.1	
6	1, 2, 7.2, 8.1	
7	1, 2, 8.1	

Acknowledgements

Members of Technical Committee on Disposable Single Use Devices

Mr Ahmad Sharif Hambali (Chairman)	Ministry of Health Malaysia (Medical Device Bureau)
Mr Mohammad Nazmin Noh (Secretary)	SIRIM Berhad
Assoc Prof Jaafar Md Zain	Academy of Medicine of Malaysia
Mr Lim Hong Peng/ Mr Daniel Lim	Association of Malaysia Medical Industries
Dr Zainah Sa'at	Institute for Medical Research
Ms Yap Siow Ling	Institute of Quality Malaysia
Mr Lee Teong Heng	Malaysia Medical Device Association
Dr Lee Yau Leong	Malaysian Medical Association
Ms Rohaizah Ahmad	Malaysian Nuclear Agency
Dr Mok Kok Lang	Malaysian Rubber Board
Datin Wan Muji Wan Ngah/ Ms Yeoh Saw See	Malaysian Sterile Service Association
Ms Sasikala Thangavelu/ Mr Mohd Zulhisham Junaidi	Ministry of Health Malaysia (Medical Device Bureau)
Dr Lim Chiao Mei	Pusat Penyelidikan Klinikal (PPK)