

Medical gloves for single use —

Part 2: Requirements and testing for physical properties

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British Standard

ICS 11.140

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National foreword

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- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 10, an inside back cover and a back cover.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 December 2000

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ISBN 0 580 36698 7

Amendments issued since publication

Amd. No.	Date	Comments

English version

Medical gloves for single use - Part 2: Requirements and testing for physical properties (including Technical Corrigendum 1:1996)

Gants médicaux non réutilisables – Partie 2: Propriétés
physiques: exigences et essais (Rectificatif
Technique 1:1996 inclus)

Medizinische Handschuhe zum einmaligen Gebrauch –
Teil 2: Anforderungen und Prüfung der physikalischen
Eigenschaften (einschließlich Technische Korrektur 1:1996)

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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 455-2:1995.

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of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.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 physical properties; Part 1 addresses freedom from holes 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 test methods for physical properties of single-use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross-contamination for both patient and user.

2 Normative references

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 188

Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests.

ISO 4648

Rubber, vulcanized or thermoplastic – Determination of dimensions of test pieces and products for test purposes.

3 Terms and definitions

For the purposes of this standard the following terms and definitions apply.

3.1

medical gloves for single use

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

3.2

surgical gloves

sterile, anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than laying flat, and intended for use in invasive surgery

3.3

examination/procedure gloves

sterile or non-sterile medical gloves, which may or may not be anatomically shaped, intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material

3.4

long-cuff medical gloves

- a) surgical gloves having a minimum overall length of 300 mm
- b) examination/procedure gloves having a minimum overall length of 270 mm

3.5

seamed medical gloves; welded gloves

medical gloves manufactured by welding or otherwise bonding together flat films of material

4 Dimensions

4.1 General

When measured as described in 4.2 and 4.3 taking 13 samples from each lot, the median value obtained for the dimensions shall be as given in Table 1 and Table 2.

4.2 Length

Measure the length (dimension l , as designated in Figure 1) by freely suspending the glove with the middle finger on a vertical graduated rule having a rounded tip so as to fit the shape of the finger tip of the glove. Remove wrinkles and folds without stretching the glove. Record the minimum measured length.

NOTE For greater ease of measurement, the rule may be angled backwards slightly so that the glove is in contact with the rule.

4.3 Width

Measure the width (dimension w as designated in Figure 1), to the nearest millimetre, using a rule, with the glove placed on a flat surface. Do not stretch the glove.