

Medical gloves for single use

Part 2: Requirements and testing for physical properties

ICS 11.140

National foreword

This British Standard is the UK implementation of EN 455-2:2009+A2:2013. It supersedes BS EN 455-2:2009+A1:2011, which is withdrawn.

The UK committee, CH/205/3, recognizes that this British Standard specifies new minimum requirements for the force at break for gloves made from natural rubber latex compared to previous editions of the standard. This does not prevent Purchasers who wish to do so continuing to specify higher values in contract negotiations.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee CH/205, Non-active medical devices, to Subcommittee CH/205/3, Medical gloves.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2009

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English Version

Medical gloves for single use - Part 2: Requirements and testing for physical properties

Gants médicaux non réutilisables - Partie 2: Propriétés
physiques: Exigences et essais

Medizinische Handschuhe zum einmaligen Gebrauch - Teil
2: Anforderungen und Prüfung der physikalischen
Eigenschaften

This European Standard was approved by CEN on 3 October 2009 and includes Amendment 1 approved by CEN on 3 January 2011 and Amendment 2 approved by CEN on 8 January 2013.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 455-2:2009+A2:2013) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by DIN.

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 August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes  EN 455-2:2009+A1:2011 .

This document includes Amendment 1, approved by CEN on 2011-01-03 and Amendment 2, approved by CEN on 2013-01-08.

The start and finish of text introduced or altered by amendment is indicated in the text by tags   and  .

This document 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 document.

EN 455 consists of the following parts, under the general title *Medical gloves for single use*:

- *Part 1: Requirements and testing for freedom from holes*
- *Part 2: Requirements and testing for physical properties*
- *Part 3: Requirements and testing for biological evaluation*
- *Part 4: Requirements and testing for shelf life determination*

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