



**SLOVENSKI STANDARD**  
**SIST EN 455-2:2010/kFprA1:2010**  
**01-november-2010**

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**Medicinske rokavice za enkratno uporabo - 2. del: Zahteve in preskusi za ugotavljanje fizikalnih lastnosti - Dopolnilo**

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

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

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

**Ta slovenski standard je istoveten z: EN 455-2:2009/FprA1**

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**ICS:**

11.140      Oprema bolnišnic      Hospital equipment

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
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**FINAL DRAFT**  
**EN 455-2:2009**

**FprA1**

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ICS 11.140

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 draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

This draft amendment A1, if approved, will modify the European Standard EN 455-2:2009. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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 Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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## Foreword

This document (EN 455-2:2009/FprA1:2010) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

## EN 455-2:2009/FprA1:2010 (E)

## 1 Modification of Table 3

Replace the existing Table 3 with the following:

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Table 3 — Median values of force at break

	Force at break in Newton				
	Surgical gloves		Examination/procedure gloves		
	a)	b)	c)	d)	e)
<b>Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3</b>	≥ 9,0	≥ 9,0	≥ 6,0	≥ 6,0	≥ 3,6
a) Requirements for gloves made from natural rubber latex. b) Requirements for gloves made from all other elastomeric materials, e.g. polychloroprene, synthetic polyisoprene, nitrile, styrene block copolymers, polyurethane. c) Requirements for gloves made from elastomeric materials except nitrile, e.g. natural rubber latex, polychloroprene, synthetic polyisoprene, styrene block copolymers, polyurethane. d) Requirements for gloves made from nitrile. e) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).					

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