



SLOVENSKI STANDARD
SIST EN 455-1:2000/A1:2000
01-januar-2000

Medicinske rokavice za enkratno uporabo - 1. del: Zahteve in preskusi za ugotavljanje luknjičavosti

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

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

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

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Ta slovenski standard je istoveten z: EN 455-1:1993/A1:1998
SIST EN 455-1:2000/A1:2000
<https://standards.itteh.ai/catalog/standards/sist/255e9941-7c38-47e4-b0b1-7a0b1ec72c0f/sist-en-455-1-2000-a1-2000>

ICS:

11.140 Oprema bolnišnic Hospital equipment

SIST EN 455-1:2000/A1:2000 en

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EUROPEAN STANDARD

EN 455-1:1993/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 1998

ICS 11.140; 13.340.10

Descriptors: medical equipment, disposable equipment, protective clothing, insulating gloves, specifications, leaktightness, tests, marking

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 amendment A1 modifies the European Standard EN 455-1:1993; it was approved by CEN on 30 November 1997.

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. 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 amendment 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.

[SIST EN 455-1:2000/A1:2000](https://standards.iteh.ai/catalog/standards/sist/255e9941-7c38-47e4-b6b1-7a0b1ec72c0f/sist-en-455-1-2000-a1-2000)

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REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZNANOST IN TEHNOLOGIJO
Urad RS za standardizacijo in meroslovje
LJUBLJANA

SIST... EN 455-1 / A1

PREVZET PO METODI RAZGLASITVE

-01- 2000



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

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

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EN 455-1:1993/A1:1998

Foreword

This Amendment EN 455-1:1993/A1:1998 to EN 455-1:1993 has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This Amendment to the European Standard EN 455-1:1993 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 1998, and conflicting national standards shall be withdrawn at the latest by July 1998.

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.

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ALTERNATIVE TO THE ORIGINAL
CEN/TC 205 DOCUMENT
APPROVED BY THE CEN/TC 205
SECRETARIAT

8003 -10-



Add to the foreword:

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

Add Annex ZA.

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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/subclause 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	