



SLOVENSKI STANDARD
SIST EN 455-3:2015/oprA1:2016
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**Medicinske rokavice za enkratno uporabo - 3. del: Zahteve in preskušanje za
biološko ovrednotenje**

Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 3: Anforderungen und
Prüfung für die biologische Bewertung

Gants médicaux non réutilisables - Partie 3 : Exigences et essais pour évaluation
biologique

Ta slovenski standard je istoveten z: EN 455-3:2015/prA1

ICS:

11.140 Oprema bolnišnic Hospital equipment

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EUROPEAN STANDARD
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This draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

This draft amendment A1, if approved, will modify the European Standard EN 455-3:2015. 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-CENELEC 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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European foreword

This document (EN 455-3:2015/prA1:2016) 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 CEN Enquiry.

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).

EN 455-3:2015/prA1:2016 (E)**1 Modification to Clause 1, Scope**

Add the following note after the first paragraph:

“NOTE Medical gloves labelled as single use are medical devices for single use only according to the MDD 93/42/EEC. A single use medical device (SUMD) is intended for use on a single patient.”.

2 Modification to 4.6, Labelling

Add the following as the new bullet point a) (and renumber accordingly the remaining list entries):

"

a) Medical gloves shall be labelled for single use on a single patient:

NOTE This is in accordance with the MDD 93/42/EEC.

— for any medical glove the product labelling shall not include any term suggesting disinfection, reprocessing or re-use.”.