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Medicinska engångshandskar –
Del 3: Krav och provningsmetoder för biologisk utvärdering

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

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Europastandarden EN 455-3:2015 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 455-3:2015.

Denna standard ersätter SS-EN 455-3:2006, utgåva 2.

The European Standard EN 455-3:2015 has the status of a Swedish Standard. This document contains the official English version of EN 455-3:2015.

This standard supersedes the Swedish Standard SS-EN 455-3:2006, edition 2.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

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Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-3

April 2015

ICS 11.140

Supersedes EN 455-3:2006

English Version

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

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

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

This European Standard was approved by CEN on 24 January 2015.

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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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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 455-3:2015) 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 October 2015 and conflicting national standards shall be withdrawn at the latest by October 2015.

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 455-3:2006.

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.

With respect to EN 455-3:2006 the following changes are:

a) standard was specified to relevant parts of EN ISO 10993 for Biological evaluation of medical devices;

b) normative references revised;

c) EN 980 was replaced by EN ISO 15223-1;

d) subclause 4.2 "chemicals" was specified;

e) subclause 4.4 specified as "powder-free gloves";

f) level "As Low As Reasonably Practicable" (ALARP) removed in the whole standard;

g) subclause 4.6 "labelling" specified;

h) symbol for products containing natural latex (Figure 1) removed;

i) the references in Annex B revised;

j) Correspondence between this European Standard and Directive 89/686/EEC on Personal Protective Equipment made (see Annex ZA).

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.*

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece,

Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

Adverse reactions to proteins in latex products have been reported over several years in variable rates of prevalence. Additionally, adverse reactions due to chemicals, lubricants, sterilization residues, pyrogens or other residues are described in the scientific literature. Adverse reactions are most often reported due to gloves made from natural rubber latex, but some of the reactions can also be seen due to gloves made from synthetic polymers.

EN ISO 10993 specifies requirements and test methods for biological evaluation of medical devices. However it does not specifically address adverse reactions that can result from the use of medical gloves (e.g, immediate type allergies). These adverse reactions occur to specific allergens that can be present in gloves. Several factors contribute to the risk of reaction:

a) the duration and frequency of skin contact with gloves;

b) the exposure to the allergens through direct contact to mucosa and skin (especially when not intact) and by inhalation of particles;

c) the occlusive nature of the glove/skin interaction during glove use.

This part of EN 455 gives requirements and test methods for evaluation of the biological safety of medical gloves as part of a risk management process, in accordance with EN ISO 10993.

1 Scope

This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*

EN ISO 10993-1:2009, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)*

EN ISO 10993-5:2009, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)*

EN ISO 10993-10:2013, *Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)*

EN ISO 14971:2012, *Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 15223-1:2012, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2012)*

EN ISO 21171:2006, *Medical gloves - Determination of removable surface powder (ISO 21171:2006)*

European Pharmacopoeia, General chapter 2.6.14 Bacterial Endotoxins: publisher EDQM - Council of Europe; 7 allée Kastner, CS 30026, F-67081 Strasbourg; France http://www.edqm.eu/

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
chemicals
substances added or formed during any step of the manufacturing process or in storage which may be available in the final product

Note 1 to entry: These can include lubricants, chemical coatings and sterilizing agents. Several chemical ingredients are commonly used during processing of gloves, some of them are known to cause type IV allergic reactions. The type and amount of residual chemicals added and finally present are variable.

3.2
endotoxins
lipo-polysaccharides originating from the outer cell-membrane of Gram-negative bacteria

Note 1 to entry: Endotoxins are one type of pyrogen. Sources of endotoxins can include bacterial contamination of the raw materials, especially the process water used during manufacturing and manual handling of the gloves.

3.3
powder
all water insoluble material on the surface of a glove that is removed by washing under the conditions of the test

[SOURCE: EN ISO 21171:2006, 3.1]

Note 1 to entry: This includes both deliberately added powder and other processing aids or materials accidentally present which may be readily detached from the surface of the glove. For the purpose of this European Standard any glove containing 2 mg or less powder is a powder-free glove and more than 2 mg is a powdered glove (for requirement see 4.4.).

3.4
process limit
highest value likely to be encountered for a validated manufacturing process

3.5
proteins, allergenic
proteins capable of causing a type I allergic reaction

3.6
proteins, leachable
aqueous proteins and peptides extractable from the final product

3.7
pyrogens
substances creating fever in rabbits which can be related to fever and other adverse reactions in humans

4 Requirements

4.1 General

EN ISO 10993-1:2009 describes the general principles governing the biological evaluation of medical devices and shall be used to select the appropriate tests as described in other parts of the series. Based on EN ISO 10993-1:2009 medical gloves are classified as limited contact duration surface devices and require compliance to EN ISO 10993-5:2009 and EN ISO 10993-10:2013.

The classification of medical gloves according to EN ISO 10993-1:2009 should not be confused with the definitions provided in the medical device directives for these products.

A risk management process in accordance with EN ISO 14971:2012 shall be established.

4.2 Chemicals

Gloves shall not be dressed with talcum powder (magnesium silicate).

The manufacturer shall disclose, upon request, a list of chemical ingredients either added during manufacturing or already known to be present in the product such as accelerators, antioxidants and biocides that are known to cause adverse health effects based on current data.

Upon request the manufacturer shall provide evidence of the steps taken to reduce the risk to the end-user of exposure to chemicals used in the manufacturing process which, based on current data, are known to cause adverse health effects.

Manufacturers may only declare the absence of a substance if the substance is not used in any part of the manufacturing process. No compounds shall be used in the manufacture of the product that is known to form a substance that is subject of such a declaration.