ILNAS

Institut luxembourgeois de la normalisation
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des produits et services

ILNAS-EN 455-3:2006

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

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National Foreword

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This European Standard was approved by CEN on 13 October 2006.

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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 Central Secretariat has the same status as the official versions.

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Foreword

This document (EN 455-3:2006) 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of an identical text or by endorsement, at the latest by June 2007, and conflicting national standards shall be withdrawn at the latest by June 2007.

This document supersedes EN 455-3:1999.

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 93/42/EEC.

For relationship with EU Directive, 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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and 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 14971 and 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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN ISO 10993 (all parts), *Biological evaluation of medical devices*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2000)*

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

European Pharmacopoeia, Monograph 2.6.14 Bacterial Endotoxins: publisher EDQM Council of Europe; 226 avenue de Colmar B.P. 907; F-67029 Strasbourg; France http://www.pheur.org

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 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 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

[EN ISO 21171:2006, definition 3.1]

NOTE 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

Medical gloves for single use shall be evaluated as described in the EN ISO 10993 series. Part 1 of this series 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.

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