SVENSK STANDARD
SS-EN 455-4:2009

Fastställd/Approved: 2009-08-10
Publicerad/Published: 2009-09-15
Utgåva/Edition: 1
Språk/Language: engelska/English
ICS: 11.140

Medicinska engångshandskar –
Del 4: Krav och provningsmetoder för lagringsegenskaper

Medical gloves for single use –
Part 4: Requirements and testing for shelf life determination

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-4

July 2009

ICS 11.140

English Version

Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

Gants médicaux non réutilisables - Partie 4: Exigences et essais relatifs à la détermination de la durée de conservation

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 4: Anforderungen und Prüfung zur Bestimmung der Mindesthaltbarkeit

This European Standard was approved by CEN on 20 June 2009.

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Ref. No. EN 455-4:2009: E

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Foreword

This document (EN 455-4:2009) 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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by January 2010.

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 part of EN 455 gives requirements and test methods for shelf life determination of medical gloves as part of a risk management process, in accordance with EN ISO 14971. 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

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 EC Directive 93/42/EEC.

For relationship with EC Directive 93/42/EEC, see informative Annex ZA, which is an integral part of this document.

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, 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 the United Kingdom.

Introduction

Medical Gloves are intended to be a barrier to agents responsible for the transmission of infections. In order to help ensure effectiveness, it is essential that gloves fit the hand properly, are free from holes and have adequate physical strength so as not to fail during use. All these issues are addressed in the EN 455 series.

This European Standard covers the minimum properties that address certain essential requirements detailed in the Medical Devices Directive (93/42/EEC). Manufacturers are required to conduct stability tests to estimate the shelf life of any new or modified glove before the product is placed on the market and to initiate real time stability studies. The real time stability test can be considered as part of the manufacturers' requirement to conduct post-marketing surveillance on their products. These requirements are intended to ensure that manufacturers have adequate data to support shelf life claims before products are placed on the market and that these data are available for review by regulatory authorities.

1 Scope

This part of EN 455 specifies requirements for shelf life for medical gloves for single use. It also specifies the requirements for labelling and the disclosure of information relevant to the test methods used.

This European Standard applies to existing, new and significantly changed designs. Existing designs that do not currently have ageing data available should generate that data within a reasonable period of time.

This European Standard does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

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 455 (all parts), *Medical gloves for single use*

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

EN ISO 11607 (all parts), *Packaging for terminally sterilized medical devices*

3 Terms and definitions

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

3.1
Arrhenius equation
relation between the activation energy (E_A), the absolute temperature (T), and the rate constant of a degradation reaction [k(T)]

NOTE The shelf life of a rubber product is predicted based on the Arrhenius principle of chemical reaction rates. The Arrhenius equation has the basic form:

$$k(T) = A \cdot e^{\frac{-E_A}{RT}}$$

where

A = constant (min^{-1}),

E_A = Activation Energy (J/mol),

R = the Universal Gas Constant (8,314 $J \cdot mol^{-1} \cdot K^{-1}$),

T = Absolute Temperature (K),

$k(T)$ (min^{-1}) is the rate constant for the degradation process.

An alternate way of expressing the Arrhenius equation is:

$$\ln k(T) = \ln A - (\frac{E_A}{RT})$$

The time required for the physical properties to deteriorate to the threshold value is inversely proportional to the rate constant *k(T)*.

3.2
consumer package
package, intended for distribution to a consumer, containing loose gloves or individual pairs of gloves

NOTE For example a primary pack (peelpack) for sterile product or a dispenser box for non-sterile product.

3.3
expiry date
stated date after which the gloves shall not be used

3.4
lot
collection of gloves of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed in the same type of individual container

3.5
shelf life
time from date of manufacture to the claimed expiry date

3.6
significant change
change that could reasonably be expected to impact the safety or effectiveness of a medical device

NOTE It could include a change to any of the following:

a) the manufacturing process, facility or equipment;

b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;

c) the design of the device, including its performance characteristics, principles of operation and specifications of materials; and

d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry date.

3.7
threshold value
maximum or minimum value for a property being tested

4 Requirements

4.1 General

Medical gloves shall comply with the requirements of the EN 455 series of standards until the end of their stated shelf life provided they are stored according to the instructions supplied by the manufacturer.

Manufacturers shall test the properties that are reasonably expected to alter over the shelf life of the product. These properties shall include, but are not limited to, force at break, freedom from holes and, in the case of sterile gloves, pack integrity. This European Standard defines the methods to determine shelf life of medical gloves before any new product or products for which there has been a significant change to formulation or process can be marketed.

Since it is impracticable to complete real time ageing studies before introducing products to the market, accelerated stability studies based on kinetic principles can be used to assign a provisional shelf life. Such provisional shelf lives assigned shall be verified by real time studies.

Shelf life claims based on accelerated ageing shall not exceed three years. Data supporting the shelf life claims made by the manufacturer shall be made available on request.

4.2 Shelf life and resistance to degradation

Before a new or significantly modified product is placed on the market this European Standard requires:

— a completed real time study as described in 5.1 to determine shelf life or

— a real time study as described in 5.1 to determine shelf life shall have commenced and an accelerated ageing study as described in 5.2 shall have been completed.

It is recommended that the shelf life should be determined at the specific storage conditions specified for the product by the manufacturer (e.g. 25 °C). The manufacturer shall state the temperature along with the shelf life or expiry date. Accelerated ageing studies (5.2) shall be carried out on gloves from the same production lots as used for real time determination of shelf life (5.1).

NOTE For guidance on mean kinetic temperature see EN ISO 291.

4.3 Product changes

Whenever there is any significant change to the product the manufacturer shall re-determine shelf life.

4.4 Labelling

At the end of the shelf life the labelling shall remain readable according to EN 1041.

4.5 Sterile barrier integrity

For sterile products the requirements of EN ISO 11607 series apply. Attention is drawn to the maintenance of the sterility for the given shelf life of the product.

NOTE Depending on the utilised packaging material, it might occur that the packaging material will not withstand certain elevated temperatures that are being used to predict the shelf life by means of accelerated ageing testing. In these cases it might be advisable to conduct the accelerated ageing testing at lower temperatures.

4.6 Storage conditions

Manufacturers shall provide storage instructions to the end user. These may be printed on the consumer package or supplied in an accompanying document.

5 Test methods

5.1 Real time shelf life determination

The test method for the determination of shelf life using real time studies shall be that given in Annex A or a suitably validated method that has been shown to be equivalent to Annex A.

If the real time data indicates a shorter shelf life than that claimed on the basis of accelerated ageing the manufacturer shall notify the relevant regulatory authorities. The manufacturer shall change the shelf life claims for