სსტ ენ 455-4:2009/2020

საქართველოს სტანდარტი

სამედიცინო ხელთათმანები ერთჯერადი გამოყენებისათვის - ნაწილი 4: მოთხოვნები და გამოცდები შენახვის ვადის განსაზღვრისათვის

საქართველოს სტანდარტებისა და მეტროლოგიის
ეროვნული სააგენტო
თბილისი

სსტ ენ 455-4:2009/2020

საინფორმაციო მონაცემები

1 შემუშავებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს სტანდარტების დეპარტამენტის მიერ

2 დამტკიცებულია და შემოღებულია სამოქმედოდ საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს 2020 წლის 23 მარტის №37 განკარგულებით

3 მიღებულია გარეკანის თარგმნის მეთოდით სტანდარტიზაციის ევროპული კომიტეტის სტანდარტი ენ 455-4:2009 "სამედიცინო ხელთათმანები ერთჯერადი გამოყენებისათვის - ნაწილი 4: მოთხოვნები და გამოცდები შენახვის ვადის განსაზღვრისათვის"

4 პირველად

5 რეგისტრირებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს რეესტრში: 2020 წლის 23 მარტი №268-1.3-016917

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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

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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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by January 2010.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.