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Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

EESTI STANDARDIKESKUS
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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 14079:2003 sisaldab Euroopa standardi EN 14079:2003 ingliskeelset teksti.	This Estonian standard EVS-EN 14079:2003 consists of the English text of the European standard EN 14079:2003.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.04.2003.	Date of Availability of the European standard is 23.04.2003.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

Dispositifs médicaux non actifs - Exigences de performance et méthodes d'essais pour la gaze de coton absorbante et la gaze de coton et viscose absorbante

Nichtaktive Medizinprodukte - Leistungsanforderungen und Prüfverfarhen für Verbandmull aus Baumwolle und Verbandmull aus Baumwolle und Viskose

This European Standard was approved by CEN on 21 February 2003.

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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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 14079:2003) has been prepared by Technical Committee CEN /TC 205, "Non-active medical devices" the secretariat of which is held by BSI.

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 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

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.

This standard is based on the European Pharmacopoeia monographs. As charged by CEN/TC 205 it is a mere reformatting of the monographs. It includes requirements and test methods as far as they are in line with the essential requirements as defined in Annex I of the Medical Device Directive 93/42/EEC. This standard does not describe the full state of the art and therefore will be revised immediately after finalization.

Annexes A and B are normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Absorbent cotton gauze, absorbent cotton ribbon gauze and absorbent cotton and viscose ribbon gauze were described in the European Pharmacopoeia. Due to the introduction of the Medical Device Directive 93/42/EEC, those monographs have been removed from the European Pharmacopoeia.

1 Scope

This standard describes the requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauzes. The standard does not consider gauzes impregnated with a pharmaceutical substance.

2 Normative references

This standard contains no normative references

3 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply:

3.1
absorbent cotton gauze
cotton cloth of plain weave, bleached to a good white and purified, being white and practically odourless, containing not more than slight traces of leaf, pericap seed-coat or other impurities and reasonably free from weaving defects

3.2
absorbent cotton ribbon gauze
woven cloth supplied in continuous ribbons of various widths with fast selvedges, made from cotton threads that are purified, bleached and made absorbent either before or after weaving, being white and practically odourless, containing not more than slight traces of leaf, pericap seed-coat or other impurities and reasonably free from weaving defects

3.3
absorbent cotton and viscose ribbon gauze
woven cloth supplied in continuous ribbons of various widths with fast selvedges, having in the warp cotton threads and in the weft viscose threads or combined cotton and viscose threads, made from threads that are purified, bleached and made absorbent either before or after weaving, being white and practically odourless, containing not more than slight traces of leaf, pericarp seed-coat or other impurities and reasonably free from weaving defects

4 Requirements

4.1 Fibre Identification

4.1.1 Absorbent cotton gauze and absorbent cotton ribbon gauze

When tested according to 5.2.1 the cotton fibres shall conform to the IDENT tests A, B and C.

4.1.2 Absorbent cotton and viscose ribbon gauze

When tested according to 5.2.2 the cotton fibres shall conform to the IDENT tests A and C and the viscose fibres shall conform to IDENT test B.

If it is necessary to differentiate between lustrous or matt viscose, the IDENT test D shall be used.

4.2 Acidity and alkalinity

When tested according to 5.3 neither solution shall be pink.