

**MITTEAKTIIVSED MEDITSIINISEADMED. NÕUDED JA
KATSEMEETODID ABSORBEERIVALE PUUVILLASELE
MARLILE NING ABSORBEERIVALE PUUVILL-
VISKOOSMARLILE**

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

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.

ICS 11.120.20

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Aru 10, 10317 Tallinn, Eesti; koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

ICS 11.120.20

English version

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 Prüfverfahren für Verbandmull aus Baumwolle und Verbandmull aus Baumwolle und Viskose

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

page

Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Requirements	5
4.1 Fibre Identification	5
4.2 Acidity and alkalinity	5
4.3 Foreign fibres	6
4.4 Fluorescence	6
4.5 Thread count	6
4.6 Mass per square metre	7
4.7 Minimum breaking load	7
4.8 Sinking time	7
4.9 Ether-soluble substances	7
4.10 Surface active substances	7
4.11 Water-soluble substances	7
4.12 Starch and dextrin	7
4.13 Extractable colouring matter	7
4.14 Loss on drying	7
4.15 Sulphated ash	8
5 Test methods	8
5.1 General	8
5.2 Fibre identification	8
5.3 Test method for acidity or alkalinity	9
5.4 Test method for foreign fibres	10
5.5 Test method for fluorescence	10
5.6 Test method for thread count	10
5.7 Test method for mass per square metre	10
5.8 Test method for minimum breaking load	10
5.9 Test method for sinking time	11
5.10 Test method for ether soluble substances	11
5.11 Test method for surface active substances	11
5.12 Test method for water-soluble substances	11
5.13 Test method for starch and dextrin	11
5.14 Test methods for extractable colouring matter	12
5.15 Test method for loss on drying	12
5.16 Test method for sulphated ash	12
6 Test report	12
Annex A (normative) Reagents to determine the degree of coloration of liquids	13
A.1 Primary solutions	13
A.2 Standard solutions	14
A.3 Reference solutions	14
Annex B (normative) Preparation of test solution S	17
Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	18

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.

This document is a preview generated by EVS

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, pericarp 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 selvages, 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, pericarp 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 selvages, 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.