# Medical gloves - Determination of removable surface powder

Medical gloves - Determination of removable surface powder

**EESTI STANDARDI EESSÕNA** **NATIONAL FOREWORD**

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| Käesolev Eesti standard EVS-EN ISO 21171:2006 sisaldab Euroopa standardi EN ISO 21171:2006 ingliskeelset teksti.<br><br>Käesolev dokument on jõustatud 29.06.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.<br><br>Standard on kättesaadav Eesti standardiorganisatsioonist. | This Estonian standard EVS-EN ISO 21171:2006 consists of the English text of the European standard EN ISO 21171:2006.<br><br>This document is endorsed on 29.06.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.<br><br>The standard is available from Estonian standardisation organisation. |

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|---|---|
| **Käsitlusala:**<br>This International Standard specifies methods for the determination of readily removable powder on the surface of gloves for medical use. Three methods are specified: method A for powdered gloves and methods B and C for powder-free gloves. This International Standard does not address safety issues that may be associated with the presence of powder on gloves nor does it prescribe limits on the amounts that may be present. The applicability of this International Standard to medical gloves not made from rubber has not been established. | **Scope:**<br>This International Standard specifies methods for the determination of readily removable powder on the surface of gloves for medical use. Three methods are specified: method A for powdered gloves and methods B and C for powder-free gloves. This International Standard does not address safety issues that may be associated with the presence of powder on gloves nor does it prescribe limits on the amounts that may be present. The applicability of this International Standard to medical gloves not made from rubber has not been established. |

**ICS** 11.140

**Võtmesõnad:**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 21171

May 2006

ICS 11.140



English Version

## Medical gloves - Determination of removable surface powder (ISO 21171:2006)

Gants à usage médical - Détermination de la poudre de surface amovible (ISO 21171:2006)

Medizinische Handschuhe - Bestimmung des entfernbaren Oberflächenpuders (ISO 21171:2006)

This European Standard was approved by CEN on 3 April 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of 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.

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

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Ref. No. EN ISO 21171:2006: E

## Foreword

This document (EN ISO 21171:2006) has been prepared by Technical Committee ISO/TC 45 "Rubber and rubber products" in collaboration with 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 November 2006, and conflicting national standards shall be withdrawn at the latest by November 2006.

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.

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.

### Endorsement notice

The text of ISO 21171:2006 has been approved by CEN as EN ISO 21171:2006 without any modifications.

# ANNEX ZA
(informative)

## Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to essential requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

**Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC**

| Clauses of this European Standard | Corresponding essential requirements (ERs) of EU Directive 93/42/EEC |
|---|---|
| 4, 5, 6, 7, 8, 9, 10, 11 | ISO 21171 is a test method and does not contain requirements for medical gloves. Hence it cannot of itself support any essential requirement of Directive 93/42/EEC but, in conjunction with a device specification, it addresses ER 1, 2, 7.1, 7.2 and 7.3. |

**WARNING:** Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

INTERNATIONAL STANDARD

**ISO 21171**

First edition
2006-05-01

# Medical gloves — Determination of removable surface powder

*Gants à usage médical — Détermination de la poudre de surface amovible*



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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21171 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 3, *Raw materials (including latex) for use in the rubber industry*.

This International Standard is based on ASTM D 6124-01, *Standard Test Method for Residual Powder on Medical Gloves*, copyright ASTM, used with permission of ASTM.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.



 

## Introduction

Depending on their method of manufacture, some medical gloves can have on their surface a small amount of powder, normally modified corn-starch, which is intended to assist donning. Current thinking is that the presence of excessive amounts of such powder can present a health hazard. The methods for the determination of removable surface powder in this International Standard are based on those given in ASTM D 6124-01, from which they differ in the method for determining removable powder from powder-free surgeon's gloves and in the precision data.

# Medical gloves — Determination of removable surface powder



**WARNING — Persons using this International Standard should be familiar with normal laboratory practice. This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.**

## 1 Scope

This International Standard specifies methods for the determination of readily removable powder on the surface of gloves for medical use. Three methods are specified: method A for powdered gloves and methods B and C for powder-free gloves. This International Standard does not address safety issues that may be associated with the presence of powder on gloves nor does it prescribe limits on the amounts that may be present. The applicability of this International Standard to medical gloves not made from rubber has not been established.

## 2 Principle

The surfaces of a glove are washed with water to remove the water-insoluble powder which is then determined by filtration followed by weighing. The number of gloves used for the procedure depends on whether the gloves are nominally powder-free or powdered.

## 3 Terms and definitions

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

**3.1**
**powder**
all water-insoluble material on the surface of a glove that is removed by washing under the conditions of the test

**3.2**
**powdered gloves**
gloves for which a powder has been used as a part of the manufacturing process, generally to facilitate donning, and described by the manufacturer as “powdered”

**3.3**
**powder-free gloves**
gloves which are described by the manufacturer as “powder-free”

NOTE Gloves should always be clearly labelled as to whether they are powdered or powder-free (unlabelled gloves would normally be unacceptable to consumers). Nevertheless, if a sample of gloves does not carry the designation “powdered” or “powder-free”, the gloves should be analysed as if they were powdered.