ILNAS

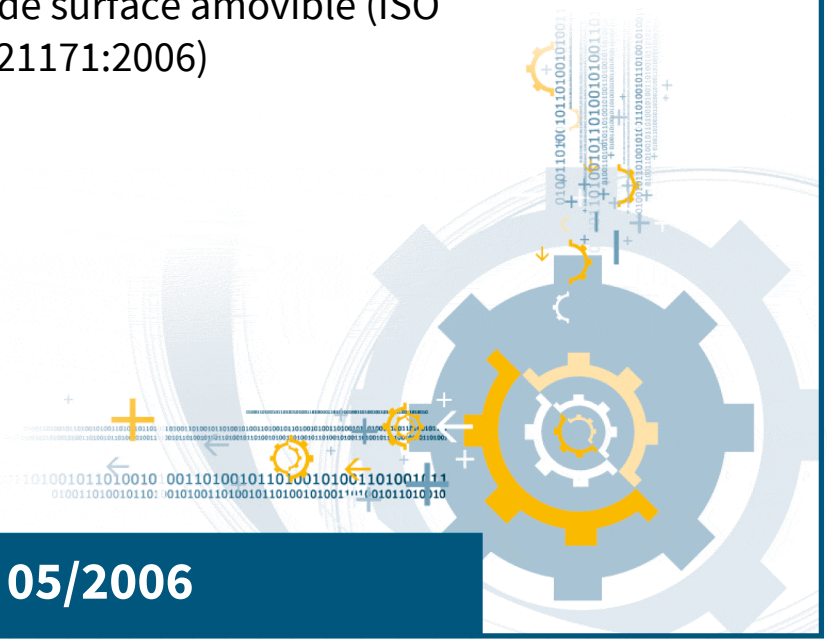
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 21171:2006

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

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

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



05/2006

National Foreword

This European Standard EN ISO 21171:2006 was adopted as Luxembourgish Standard ILNAS-EN ISO 21171:2006.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 21171

May 2006

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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.