INTERNATIONAL STANDARD

ISO 21171

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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.

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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.