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

Reference number
ISO 21171:2006(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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.

4 Apparatus

Normal laboratory glassware and tweezers, together with the following:

4.1 **Balance**, accurate to 0,1 mg.

4.2 **Mechanical shaker**, capable of a minimum oscillation frequency of 1,7 Hz (102 cycles/min).

4.3 **Drying oven**, capable of maintaining 100 °C ± 5 °C.

4.4 **Filters**, 90 mm and 47 mm glass microfibre filters of 2,7 µm pore size, together with suction filtration apparatus.

4.5 **Desiccator**.

5 Reagents

5.1 Wherever water is called for, distilled or deionized water shall be used.

6 Sampling

Randomly select an appropriate number of gloves from each lot to be evaluated. For determinations on powdered gloves, use two gloves and for determinations on powder-free gloves use five gloves *except* in the case of surgeon's gloves for which use three pairs (i.e. six gloves).

7 Method A — Procedure for powdered gloves

7.1 Before use, rinse all glassware and tweezers with water.

7.2 The test shall be carried out at 25 °C ± 5 °C on two gloves randomly selected.

7.3 Take a 90 mm, 2,7 µm pore size filter and place it in the desiccator for not less than 30 min. Remove the filter and immediately weigh it on the balance, determining the mass to the nearest 0,1 mg. Record the mass in grams (m_0).

NOTE The use of a PTFE (polytetrafluoroethylene) base is suggested if experience shows that there is a risk of tearing the filter on removal from a glass surface.

7.4 Place the filter in the suction apparatus.

7.5 Carefully remove a glove from its packaging and insert it into a 1 l capacity conical flask, or other suitable container, containing 500 cm^3 of water so that 1 cm to 3 cm of the cuff projects out round the rim of the flask. Pour approximately 250 cm^3 of water into the glove while holding a small portion of the cuff away from the rim of the flask to allow air to be vented from the flask. While pouring the water into the glove ensure that the projecting part of the cuff is rinsed. Tightly seal the flask with a rubber stopper covered by a small piece of polypropylene sheet so that the flask does not leak. Place the sealed flask in the mechanical shaker and oscillate for 30 s at a speed of not less than 1,7 Hz. Ensure that all the surfaces of the glove are well washed.

7.6 Take the flask from the shaker and remove the stopper. Pour the water from inside the glove through the filter in the suction filtration unit. Remove the glove from the flask and pour any remaining water from inside the glove through the filter, followed by the water in the flask.

7.7 Using the same glove repeat the procedure of 7.5 and 7.6 with a further 500 cm^3 of fresh water in the flask and 250 cm^3 in the glove.

7.8 Repeat the procedure of 7.7 twice more, to make a total of four fresh water rinses for a single glove. Finally, rinse the flask and stopper covering with fresh water, to ensure that all material on them has been transferred to the filter.

7.9 Using a second glove repeat the procedure of 7.5 to 7.8 (in the case of surgeon's gloves, use the other one of the pair).

7.10 Remove as much water from the filter as possible by suction. Discard the filtrate. Carefully remove the filter and transfer it to a washed and dried watch glass or Petri dish. Dry in an oven at 100 °C ± 5 °C for 1 h then transfer to the desiccator to cool for not less than 30 min. Weigh the filter immediately after removal from the desiccator to minimize re-adsorption of moisture. Record the mass, in grams, to the nearest 0,1 mg (m_1).

8 Calculation of the result (method A)

The mass of powder, in milligrams, on the two gloves is given by

$$(m_1 - m_0) \times 1\,000$$

The average mass (m_A) of powder per glove, in milligrams, is given by

$$m_A = \frac{m_1 - m_0}{2} \times 1\,000$$

9 Methods B and C — Procedure for “powder-free” gloves

9.1 General

The procedure to be used for “powder-free” gloves is generally similar to that described above (see Clause 7). However, it employs a smaller filter and five gloves, except in the case of surgeon's gloves when six are used (see the Note) and the same water is used for rinsing each of them. Because only a small amount of powder should be present, it is also necessary to run a blank.

NOTE Surgeon's gloves are packaged in pairs. As the right hand and the left hand are not normally produced at the same time, it is important to test the same number of each hand.

9.2 Method B — Procedure for “powder-free” gloves other than surgeon's gloves

9.2.1 Before use, rinse all glassware and tweezers with water.

9.2.2 The test shall be carried out at 25 °C ± 5 °C on five gloves randomly selected.

9.2.3 Take a 47 mm, 2,7 µm pore size filter. Transfer it to the suction apparatus, rinse it with three portions of 50 cm^3 of water and suck free of water. Place the filter on a watch glass or Petri dish and dry it in an oven at 100 °C ± 5 °C for 1 h. Transfer the filter to a desiccator to cool for at least 30 min before use. Remove the filter and immediately weigh it on the balance, determining the mass to the nearest 0,1 mg. Record the mass in grams (m_0).

NOTE The use of a PTFE (polytetrafluoroethylene) base is suggested if experience shows that there is a risk of tearing the filter on removal from a glass surface.

9.2.4 Place the filter in the suction apparatus.