SLOVENSKI STANDARD
SIST EN 455-1:2000

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Medicinske rokavice za enkratno uporabo - 1. del: Zahteve in preskusi za ugotavljanje luknjičavosti

Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 1: Anforderungen und Prüfung auf Dichtheit

Gants médicaux non réutilisables - Partie 1: Détection des trous - Prescriptions et essais

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English version

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Foreword

This part of this European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices" of which the secretariat is held by BSI.

This European Standard applies to medical gloves for single use and has been prepared in two parts. This part addresses freedom from holes; Part 2 addresses physical properties. A third part addressing biological safety is under consideration.

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of an identical text or by endorsement, at the latest by June 1994, and conflicting national standards shall be withdrawn at the latest by October 1995.

In accordance with the CEN/CENELEC Internal Regulations, following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

1 Scope

This Part of this Standard specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.

NOTE: Attention is drawn to prEN 374. 'Protective gloves against chemicals and micro-organisms'.

2 Normative reference

This European Standard incorporates, by dated or undated reference, provisions from another publication. This normative reference is cited at the appropriate place in the text and the publication is listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

ISO 2859-1: 1989 Sampling procedures for inspection by attributes. Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

3 Definition

For the purposes of this standard the following definition applies.

Medical gloves for single use: Gloves intended for use in the medical field to protect patient and user from cross-contamination.

4 Requirement

Medical gloves for single use shall not leak when tested in accordance with clause 5.

5 Watertightness test for detection of holes

5.1 Referee testing

Vertically position a filling tube of dimensions shown in figure 1 or of dimensions to fit the glove and such that the tube is capable of holding any of the 1000 ml of water that may exceed the natural fill volume of the glove.

Attach the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secure it by suitable means to obtain a watertight seal without damaging the glove (see figure 1).

Add (1000 ± 50) ml of water at a temperature of (15 to 35) °C into the open end of the filling tube, allowing the water to pass freely into the glove.

NOTE : Some of the water may remain in the filling tube depending on the glove being tested.

Immediately inspect the glove visually for water leakage. Allow the glove to hang and visually inspect the glove for water leakage again after a period of 2 min to 3 min.

If, because of distension of the glove, the water does not rise to within 40 mm of the cuff end, raise the glove after the second inspection by a suitable means until the water level reaches 40 mm from the cuff end. Inspect visually the previously untested portion of the glove after a further period of 2 min to 3 min.

Disregard leakages within 40 mm of the cuff.

5.2 Routine testing

Routine testing shall be either by the watertightness test given in 5.1 or by another test which is validated against this test.

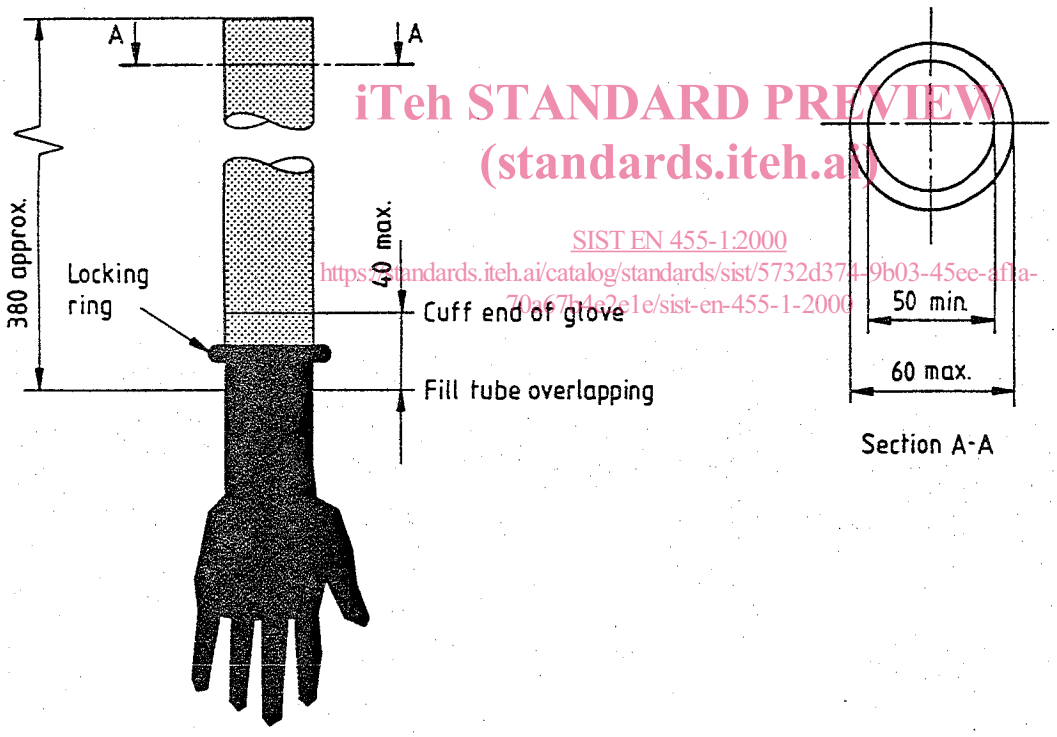
6 Sampling, inspection level and AQL

For testing batches of gloves in accordance with 5.1 for referee purposes, the sample size and allowable number of nonconforming gloves in the sample shall be determined in accordance with **ISO 2859-1:1989 using** General Inspection level 1 with an AQL of 1,5.

7 Test report

The test report shall include at least the following information:

- a reference to this standard;
- the type of gloves and manufacturing batch code;
- the name and address of the manufacturer and distributor and test laboratory;
- the date of the test performed;
- the test results.



Dimensions in millimetres

Figure 1: Watertightness test example of filling tube