
Natural rubber latex cleanroom gloves — Specification

*Gants pour salle blanche en latex de caoutchouc naturel -
Spécifications*

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

Introduction

Cleanroom gloves have long been used in the critical environments of the electronic, disk drive, semiconductor, as well as storage media industries. The quest for a cleaner glove, in new emerging industries of thin-film transistor (TFT), liquid-crystal display (LCD), nanotechnology, bio-medical applications, has ensured that this is a growing market.

The basic function of cleanroom gloves is to ensure minimal transfer of contaminants onto the products or components being processed or manufactured in a clean environment. Such contaminants will always be present in the exposed hands of the personnel. It is for this purpose that the hands need to be gloved. However, such gloves must have minimal contaminants on its surface, thus the need for the use of cleanroom gloves.

The principal contaminants that could compromise the quality or the integrity of the product or process in a critical environment are submicron particles, ionic chemical contaminants, non-volatile chemical components, as well as silicone, amide or dioctyl phthalate (DOP). In the cleanroom industry, these parameters are known as particle count, ionic content, total non-volatile residue (TNVR) and silicone, amide or DOP content.

Depending on the criticality of the operational environment, the appropriate cleanroom glove will need to be used. Hence, a very critical environment (ISO 4 cleanroom) will need the usage of the cleanest glove, i.e. ISO 4 cleanroom glove.

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Natural rubber latex cleanroom gloves — Specification

1 Scope

This document gives the specification for ISO 4, ISO 5 and ISO 6 cleanroom gloves. It is applicable to cleanroom gloves made of natural rubber latex (NRL).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEST RP-CC005.4, *Gloves and finger cots used in cleanrooms and other controlled environments*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 cleanroom

specially built room, with non-particle releasing as well as non-particle adsorbing floor and walls

Note 1 to entry: The air in circulation is filtered either through high efficiency particulate air (HEPA) or ultra-low particulate air (ULPA) filters. The primary purpose is to introduce as little contaminants as possible onto the workstations, product in progress, as well as personnel in operation, in this room.

3.2 laminar air flow

uniform pattern flow (as opposed to a turbulent flow) of air within the *cleanroom* (3.1) that ensures all dislodged *particles* (3.5) are effectively eliminated from the cleanroom

3.3 reversed osmosis deionized process water RO-DI process water

water that has very low particles as well as ionic content

3.4 resistivity

measure of resistance

Note 1 to entry: Resistivity is expressed in M Ω . It is a measure of the purity of the *RO-DI process water* (3.3). The best possible purity is 18 M Ω .

3.5 particle

object that is either solid, liquid or both, usually between 1 nm and 1 mm in size

3.6**generated particle**

particle (3.5) not previously present on the surface of a substrate but which is generated and released in response to a mechanical energy imparted on the surface

3.7**particle size**

apparent maximum linear dimension of a *particle* (3.5) in the plane of observation as observed with an optical microscope or the equivalent diameter of a particle detected by automatic instrumentation

3.8**releasable particle**

particle (3.5) present on the surface of a substrate that is readily releasable from the surface by wetting the substrate with a liquid, but without imparting mechanical energy to the substrate

3.9**airborne particle count**

number of *particles* (3.5) of size 0,3 µm and larger that are present in a typical *cleanroom* (3.1), as determined by an airborne particle counter equipment

4 Classification

Three types of cleanroom gloves are classified:

- a) ISO 4;
- b) ISO 5;
- c) ISO 6.

5 Requirements

Natural rubber latex cleanroom gloves, sampled in accordance with [Clause 6](#), shall meet the requirements specified in [Table 1](#).

Table 1 — Acceptable limit for NRL cleanroom gloves

Parameters	Acceptable limit			Test method
	ISO 6	ISO 5	ISO 4	
Particle counts	<4 000 counts/cm ²	<1 600 counts/cm ²	<800 counts/cm ²	IEST RP-CC005.4, 16.1 to 16.4
Ionic content on the glove surface:				IEST RP-CC005.4, 17.1, 17.2, 17.3
— Fluoride	<0,68 ug/cm ²	<0,38 ug/cm ²	<0,13 ug/cm ²	
— Chloride	<2,50 ug/cm ²	<1,20 ug/cm ²	<0,80 ug/cm ²	
— Bromide	<0,15 ug/cm ²	<0,09 ug/cm ²	<0,04 ug/cm ²	
— Nitrate	<2,00 ug/cm ²	<1,20 ug/cm ²	<0,60 ug/cm ²	
— Phosphate	<1,20 ug/cm ²	<0,80 ug/cm ²	<0,30 ug/cm ²	
— Sulfate	<1,80 ug/cm ²	<0,90 ug/cm ²	<0,30 ug/cm ²	
— Sodium	<0,58 ug/cm ²	<0,37 ug/cm ²	<0,13 ug/cm ²	
— Magnesium	<0,20 ug/cm ²	<0,12 ug/cm ²	<0,03 ug/cm ²	
— Potassium	<0,50 ug/cm ²	<0,30 ug/cm ²	<0,09 ug/cm ²	
— Calcium	<0,80 ug/cm ²	<0,50 ug/cm ²	<0,30 ug/cm ²	
— Ammonium	<0,35 ug/cm ²	<0,25 ug/cm ²	<0,11 ug/cm ²	

Table 1 (continued)

Parameters	Acceptable limit			Test method
	ISO 6	ISO 5	ISO 4	
Total non-volatile residue	<2,50 ug/cm ²	<15,0 ug/cm ²	<5,0 ug/cm ²	IENT RP-CC005.4, 17.1, 17.2, 17.5
Silicone	Absent	Absent	Absent	IENT RP-CC005.4, 17.1, 17.2, 17.4
Amide	Absent	Absent	Absent	
Diethyl phthalate (DOP)	Absent	Absent	Absent	

6 Sampling

For improved efficiency, it is required to sample three gloves per batch, per test parameter. Each batch is defined as the smallest quantity of gloves that undergoes a common, submicron cleaning, as well as drying. Depending on the capacity of the washers and dryers, this can vary from 6 000 pieces of gloves to 40 000 pieces of gloves. The average of the three readings shall be reported.

7 Test methods

7.1 Particle count

Refer to IEST RP-CC005.4, 16.1 to 16.4.

The counts are reported in size ranges of:

- 0,5 µm to 1,0 µm;
- 0,5 µm to 2,0 µm;
- 0,5 µm to 5,0 µm;
- 5,0 µm to 10,0 µm;
- 10,0 µm to 20,0 µm;
- >20,0 µm.

The summation of all six ranges above will be the liquid particle count for that glove, reported as counts/cm².

7.2 Ionic content

Refer to IEST RP-CC005.4, 17.1 to 17.3.

7.3 Total non-volatile residue (TNVR)

Refer to IEST RP-CC005.4, 17.1, 17.2, 17.5.

7.4 Silicone, amide and DOP content

Refer to IEST RP-CC005.4, 17.1, 17.2, 17.4.