INTERNATIONAL STANDARD

ISO 23464

First edition
2020-07

Nitrile cleanroom gloves — Specification

Reference number
ISO 23464:2020(E)

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Published in Switzerland

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Foreword

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Cleanroom synthetic gloves have been used in the critical environments of the electronic, disk drive, semiconductor as well as storage media industries, for the past 15 years. The quest for a cleaner glove, in new emerging industries of TFT, LCD, nanotechnology, bio medical applications, has ensured that this is a growing market. The industry use of cleanroom gloves is currently dominated by synthetic gloves, though, this wasn't the case, right up to the year 2000, wherein, latex gloves was the principle cleanroom available.

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 need to have minimal contaminants on its surface, thus the need for the use of cleanroom gloves.

The principle contaminants that could compromise the quality or the integrity of the product or process in a critical environment are sub-micron 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 is used. Hence, a very critical environment (Class 10 Clean Room) needs the usage of the cleanest glove, i.e. a class 10 cleanroom glove.

Nitrile cleanroom gloves — Specification

1 Scope

This document specifies the specification for ISO Class 4, ISO Class 5 and ISO Class 6 nitrile cleanroom gloves. It is applicable to cleanroom gloves made of acrylonitrile butadiene material.

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-CC005.4:2013, *Gloves and finger cots used in cleanrooms and other controlled environment*

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 https://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
RO-DI process water
reversed osmosis deionized process water
water that has very low *particles* (3.5) as well as ionic content

3.4
resistivity
measure of the resisting power of a specified material (rubber) to the flow of an electric current

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

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

For each type of material, three cleanroom gloves are classified:

a) ISO Class 4;

b) ISO Class 5;

c) ISO Class 6.

5 Requirements

Nitrile cleanroom gloves, sampled in accordance with Clause 6, shall meet the requirements specified in Table 1.

Table 1 — Acceptable limit for nitrile cleanroom gloves

Parameters	Acceptable limit			Test method
	ISO Class 6	ISO Class 5	ISO Class 4	
Particle counts (cts/cm^2)	<3 000	<1 200	<600	IEST-RP-CC005.4:2013, 16.1, 16.2, 16.3 16.4
Ionic content on the glove surface (microgram/cm^2):	<0,08	<0,03	<0,007	IEST-RP-CC005.4:2013, 17.1, 17.2, 17.3
— Fluoride				
— Chloride	<3,00	<1,20	<0,200	
— Bromide	<0,125	<0,050	<0,025	
— Nitrate	<2,500	<1,00	<0,350	
— Phosphate	<2,00	<0,800	<0,250	
— Sulphate	<2,00	<0,800	<0,300	
— Sodium	<0,100	<0,050	<0,040	
— Magnesium	<0,006	<0,004	<0,003	
— Potassium	<0,100	<0,050	<0,040	
Total non-volatile residue (microgram/cm^2)	<25,0	<10,0	<2,50	IEST-RP-CC005.4:2013, 17.1, 17.2, 17.5
Silicone	N/D	N/D	N/D	IEST-RP-CC005.4:2013, 17.1, 17.2, 17.4
Amide	N/D	N/D	N/D	
Dioctyl phthalate (DOP)	N/D	N/D	N/D	

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 cleaning as well as drying to reduce contaminants to a submicron level. 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

Apply IEST-RP-CC005.4:2013, 16.1 to 16.4.

The counts are reported in particle size ranges of:

— 0,5 µm to 1,0 µm;

— to 2,0 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 particle size ranges above shall be the liquid particle count for that glove, reported as particle counts per square centimetre.