INTERNATIONAL STANDARD



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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 (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 <u>www.iso.org/members.html</u>.

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.

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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* (<u>3.1</u>) that ensures all dislodged *particles* (<u>3.5</u>) 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 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