On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

On December 19, 2016, the FDA published a final rule banning powdered gloves based on the unreasonable and substantial risk of illness or injury to individuals exposed to the powdered gloves (https://www.federalregister.gov/documents/2016/12/19/2016-30382/banned-devices-powdered-surgeons-gloves-powdered-patient-examination-gloves-and-absorbable-powder). This guidance document has not been updated to reflect the ban. FDA is assessing how to revise this guidance to represent our current thinking on medical gloves.

# Guidance for Industry and FDA Staff

# Medical Glove Guidance Manual

**Document issued on January 22, 2008**

**This document supersedes Guidance for Medical Gloves – A Workshop Manual, September 30, 1996.**

For questions regarding this document contact the Infection Control Devices Branch Chief at (301) 796-5580.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**
**Office of Device Evaluation**
**Division of Anesthesiology, General Hospital,**
**Infection Control, and Dental Devices**
**Infection Control Devices Branch**

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# Preface

## Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

## Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1661 to identify the guidance you are requesting

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# Guidance for Industry and FDA Staff

# Medical Glove Guidance Manual

***This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.***

## Introduction

This manual provides FDA's recommendations for Premarket Notification (510(k)) submissions for medical gloves. It also provides our recommendations on how to comply with the Quality System regulation (21 CFR part 820). Previous revisions of this manual were entitled "Guidance for Medical Gloves: A Workshop Manual." This edition, the "Medical Glove Guidance Manual" (manual), supersedes all earlier revisions and explains FDA's current thinking on the requirements and recommendations for medical gloves that are marketed in the United States (U.S.).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

# 1 PRODUCT IDENTIFICATION

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## BACKGROUND

### Introduction

Medical gloves, including surgeon's and patient examination gloves, are used to prevent transmission of a wide variety of diseases to both patients and health care personnel. This manual contains information on the regulatory requirements for patient examination gloves and surgeon's gloves, as well as FDA's recommendations for meeting those requirements.

### General Controls

Medical gloves are class I reserved devices and are subject to general controls (section 513(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (Act); 21 U.S.C. 360c(a)(1)(A)), which include:

Establishment Registration
Device Listing
Premarket Notification 510(k)
Labeling
Quality System
Medical Device Reporting (MDR) – reporting of adverse events associated with a medical device.

In addition, foreign firms must name a U.S. Agent (21 CFR 807.40). You can find additional information on medical device regulatory requirements on FDA's Device Advice website at http://www.fda.gov/cdrh/devadvice/.

## PATIENT EXAMINATION GLOVES

21 CFR 880.6250 Patient examination glove.

(a) Identification. A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
(b) Classification. Class I (general controls).

**Table 1.1 Patient Examination Glove, 21 CFR 880.6250**

| Common Name | Product Code |
|---|---|
| Latex | LYY |
| Vinyl (PVC) | LYZ |
| Polymer – other than Vinyl (includes Nitrile, Polyurethane, etc.) | LZA |
| Finger Cot | LZB |
| Specialty: Chemotherapy, etc. | LZC |

The subcategories of gloves described in Table 1.1 are all special forms of the category "patient examination glove." These gloves should meet the requirements for a patient examination glove, as well as additional 510(k) and labeling recommendations described in the following paragraphs:

**Specialty/Chemotherapy Labeling Claim.** Medical gloves cleared for marketing with chemotherapy labeling claims (often referred to as chemotherapy gloves) are specialty patient examination gloves. These gloves should meet the current FDA-recognized consensus standard for patient examination gloves or an equivalent test method.
We recommend that you follow the 510(k) format for examination gloves outlined in Chapter 6 for chemotherapy glove 510(k) submissions. The 510(k) submission should also include permeation and penetration data based on actual testing with chemotherapeutic drugs.

For additional information, refer to Chemotherapy Labeling Claim in Chapter 4.

**Dental Patient Examination Gloves**. Gloves worn during dental cleaning, filling, and other dental procedures are patient examination gloves. These gloves should meet the requirements for patient examination gloves. You may use the term "dental" in the labeling of gloves intended for dentistry. The term "dental" should always be used with, and does not replace, the term "patient examination glove."

**SURGEON'S GLOVES**

21 CFR 878.4460 Surgeon's glove.

(a) Identification. A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. This excludes the lubricating or dusting powder used in the glove.

(b) Classification. Class I (general controls).

Surgeon's gloves are subject to the design control requirements of the Quality System regulation (21 CFR 820.30(a)(2)(ii)).

Surgeon's gloves should be sterile when offered for sale to end users, such as hospitals, clinics, and surgeons. FDA has not cleared any 510(k)'s for non-sterile surgeon's gloves. A 510(k) submission for surgeon's gloves should include information about the sterilization method and cycle. The provisions in 21 CFR 801.150(e) regulate the shipment of medical gloves to and from a contract sterilizer. See Chapter 8 for additional information.

**Table 1.2 Surgeon's Glove, 21 CFR 878.4460**

| Common Name | Product Code |
|---|---|
| Surgeon's Glove (including Dental Surgeon's gloves)<br>Microsurgery Glove<br>Orthopedic Surgeon's Glove<br>Autopsy Surgeon's Glove<br>Specialty/Chemotherapy Surgeon's Glove<br>Radiation Attenuating Surgeon's Gloves | KGO |

The subcategories of gloves described in Table 1.2 are all special forms of the category "surgeon's glove." These gloves should meet the requirements for a surgeon's glove as well as additional 510(k) and labeling recommendations described in the following paragraphs:

**Dental Surgeon's Glove**. You may use the term "dental" in the labeling of gloves intended for dental surgery. Gloves for dental surgery may be thicker than standard surgeon's gloves. The labeling may include the measured thickness of the gloves, but you should not use ambiguous terms such as "extra thick."

**Microsurgery Glove**. Microsurgery gloves are carefully processed to have decreased thickness in certain areas, particularly at the fingertips. To date FDA has not cleared any 510(k) submissions for microsurgery gloves that are thinner than the specifications in the FDA-recognized consensus standard for surgeon's gloves. As with all surgeon's gloves, testing should demonstrate safety and effectiveness for its indications for use.

**Orthopedic Surgeon's Glove**. Orthopedic surgical gloves may be larger, thicker, and more resistant to tear than other surgical gloves. You may state the measured thickness and other parameters of orthopedic gloves in the labeling. You should not use ambiguous terms, such as "extra thick," or "super strong."

**Autopsy Surgeon's Glove**. Autopsy gloves are intended for use during autopsy procedures and may be similar to orthopedic surgeon's gloves. These gloves are subject to the same regulatory requirements as surgeon's gloves.

**Specialty/Chemotherapy Labeling Claim.** We recommend that you follow the 510(k) format for surgeon's gloves outlined in Chapter 7 for chemotherapy glove 510(k) submissions. The 510(k) should also include permeation and penetration data based on actual testing with chemotherapeutic drugs. We recommend that surgeon's gloves with chemotherapy labeling claims follow the current FDA-recognized consensus standards for surgeon's gloves or an equivalent test method.

For additional information, refer to Chemotherapy Label Claim (under Attribute Labeling) in Chapter 4.

**Radiation Attenuating Surgeon's Glove.** Radiation attenuating surgeon's gloves are used during surgical procedures involving radiation exposure to the hands. The gloves offer some degree of protection to the hand from radiation exposure as well as protection from transmission of infectious agents. The use of these gloves includes surgical procedures that require the use of fluoroscopy or radiography. In addition to meeting the requirements for a surgeon's glove, manufacturers should have technical data to show that their attenuation claims meet the energy range of x-rays normally used in medical procedures.

## GLOVES IN KITS

A medical device kit may include medical gloves. Kit manufacturers and assemblers should assure that gloves in their kits are cleared for marketing and that the gloves can meet the appropriate FDA and ASTM standard (such as ASTM D3577, ASTM D3578, ASTM D5250, ASTM D6319) or an equivalent test method after the kit is sterilized.

We recommend that you enclose natural rubber latex gloves in their own packaging within the kit to avoid possible protein contamination of other devices. You must label the kit appropriately for any device or packaging containing natural rubber (21 CFR 801.437).

You may refer to the following documents for additional guidance:

Convenience Kits Interim Regulatory Guidance
http://www.fda.gov/cdrh/ode/convkit.html

Sterilized Convenience Kits for Clinical and Surgical Use
http://www.fda.gov/cdrh/comp/guidance/1390.html

## ACCESSORIES

### Table 1.3 Classification codes for accessories

| Common Name | Product Code | Regulation Number |
|---|---|---|
| Glove Liners/Undergloves | KGO | 21 CFR 878.4460 |
| Surgeon's Gloving Cream | KGQ | 21 CFR 878.4470 |

**Glove Liners/Undergloves**. Glove liners or undergloves are worn with patient examination or surgeon's gloves. They may be made of materials such as cotton to prevent the medical glove from contacting the user's hand, or they may be made of materials that are resistant to cutting or puncture. The glove liners provide added protection by reducing the risk of a cut or puncture wound during surgical or examination procedures and by absorbing perspiration. Unless separately classified, accessories to medical gloves have the same classification (regulation number) as the gloves with which they are used.

Medical device regulations apply to glove liners and undergloves. Because glove liners and undergloves contact the skin, you should submit biocompatibility data with a 510(k) submission to show that they are safe for their intended use (See Chapter 3, Biocompatibility). If your labeling states that your glove liners provide a protective barrier, then the glove liners should meet the quality limit for barrier defects (pinholes) in the FDA-recognized consensus standard (or an equivalent standard) for the glove to which the liner is an accessory.

**Surgeon's Gloving Cream**. Surgeon's gloving cream lubricates the user's hand before putting on a surgeon's glove. This cream may also be used with examination gloves. FDA classified gloving cream as a class I device under 21 CFR 878.4470. Gloving cream is exempt from 510(k) submission requirements unless the intended use of the cream is different from that described in 21 CFR 878.4470, i.e., "lubricating the user's hand…." Gloving creams should not degrade the glove material in latex gloves or other gloves, i.e., the creams should not be oil-based. If a manufacturer modifies the ingredients of an existing gloving cream or introduces a new gloving cream into commercial distribution, the manufacturer should ensure that the cream performs as claimed. The manufacturer also should maintain biocompatibility data on file to show that the new or modified cream is safe and effective for the intended use.

## OTHER GLOVE PRODUCTS

**Radiographic Protection Glove**. FDA classified radiographic protection gloves as a "personnel protective shield" under 21 CFR 892.6500 (product code IWP). This is a class I device and is exempt from Premarket Notification (510(k)). The gloves are intended to protect the operator, patient, or other person from unnecessary exposure to radiation during radiological procedures by providing an attenuating barrier to radiation. We recommend that you maintain technical data to show that their attenuation claims meet the energy range of x-rays normally used in medical procedures.

If radiographic protection gloves are also intended for use as medical gloves, FDA classifies them as either patient examination gloves or surgeon's gloves and they are subject to 510(k) clearance.

**Leak Detectors**. Leak detectors are chemical, electromechanical, or electronic systems designed for the glove user to monitor glove barrier integrity immediately before and during

glove use. FDA classifies these devices as accessories to medical gloves. Leak detectors used as medical devices should have 510(k) clearance before marketing.

Leak testers and other equipment used during the production of gloves are production equipment; they are not medical devices. The Quality System regulation in 21 CFR 820.70 and 820.72 covers the selection, use, control, and maintenance of production equipment.

## NON-MEDICAL GLOVES

**Embalming Gloves**. The Occupational Safety and Health Administration (OSHA) regulates embalming gloves.

**Food Service Gloves**. FDA considers food service gloves to be a food contact surface which may result in the addition of indirect food additives to the food handled. FDA's Center for Food Safety and Applied Nutrition (CFSAN) regulates food service gloves.

Gloves used for food handling or preparation are not medical devices; therefore, they are not subject to the 510(k) premarket review process and thus are not cleared for marketing by FDA's Center for Devices and Radiological Health (CDRH). Labeling of food service gloves should not, in any way, represent or suggest that they may be used for medical purposes. This may include the brand name and company name.

> For further information regarding additives and food use of gloves, contact CFSAN at 301-436-2600 (phone) or oco3@cfsan.fda.gov (email).

The National Sanitation Foundation (NSF) has developed a protocol for food service gloves identified as "P155: Disposable Food Contact Gloves." This document is available at http://www.nsf.org/.

**Cleaning Gloves.** FDA does not regulate gloves that are used for routine janitorial functions in medical facilities. However, gloves that are used for cleaning patients, or cleaning or handling surfaces or items contaminated with patient waste or fluids are medical gloves and should meet the requirements for patient examination gloves.

Utility, industrial, or general purpose gloves are used for tasks that do not involve contact with patients or body fluids. Therefore, FDA does not regulate them as medical devices. It is illegal for manufacturers to relabel these gloves for medical use or to imply in their labeling that the gloves are suitable for medical use. Labeling of utility, industrial, and general purpose gloves should not, in any way, represent or suggest that they may be used for medical purposes. This may include the brand name and company name.

# 2 GLOVE LUBRICANTS

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## ABSORBABLE DUSTING POWDER

Donning lubricants such as cornstarch and silicone may make it easier to put on medical gloves. Powdered lubricants are also called donning powders or dusting powders. Powder from medical gloves directly contacts wounds, body cavities, and skin and can contaminate both the patient's and the user's environment. FDA believes it is important to minimize the amount of powder on finished gloves. We recommend that you establish a specification for the amount of powder on a glove and a procedure to verify that powder levels on finished gloves meet that specification.

A small amount of silicone or other lubricant is also used on some powder-free gloves to aid in donning. If used, the lubricants should be on the finished gloves when you conduct biocompatibility tests. You should identify the complete chemical characterization/chemical formulation of the lubricant in the 510(k) submission.

**Examination Gloves.** Cornstarch that meets the specification for absorbable donning or dusting powder in the United States Pharmacopeia (U.S.P.) is a commonly used lubricant for examination gloves. Any powder used for lubricating examination gloves should meet the U.S.P. monograph for absorbable dusting powder or be equivalent in terms of safety and effectiveness. The 510(k) submission should state the type, specifications, and source of powder or other donning lubricant used on the gloves. You should not use talc, cotton flock, and other non-absorbable materials as a lubricating, dusting, or donning powder. Recognized consensus standards specify that the inside and outside surface of medical gloves be free of talc. Lycopodium (club moss spores) and ground pine pollen are toxic. You should not use them as powder on or in medical gloves.

**Surgeon's Gloves.** Absorbable dusting powder for lubricating a surgeon's glove is a transitional device (a device formerly regulated as a new drug before l976). FDA classifies it as a class III medical device under 21 CFR 878.4480 (product code KGP). Absorbable dusting powder for lubricating a surgeon's glove requires an approved Premarket Approval Application (PMA) or, if marketed prior to May 28, l976, a New Drug Application (NDA). You may use only absorbable dusting powders manufactured under an approved PMA or NDA on powdered surgeon's gloves.

A current list of approved NDAs or PMAs for Surgical Dusting Powder is available through the PMA database on the FDA website. Place KGP in the Product Code box and click on Search.

PMA database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

Guidance on the content and format for a PMA for Absorbable Powder for Lubricating a Surgeon's Glove is available at:

> Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove
> http://www.fda.gov/cdrh/ode/guidance/1230.html
>
> Device Advice PMA
> http://www.fda.gov/cdrh/devadvice/pma/

## COAGULANTS AND RELEASE AGENTS

In order to have uniform distribution of the latex mix on the mold, commonly called a "former," the mold is first dipped in a coagulant solution usually containing a calcium salt in water. In addition, the coagulant solution sometimes contains a lubrication agent to facilitate stripping (removing) the gloves from the molds at the end of the production line. A small amount of the coagulant and release agent remains on the "inside" surface of the glove. In some processes, washing removes most of the mold release agent from the surface of the glove. If these manufacturing material residues can adversely affect the safety or effectiveness of the gloves, you must establish and maintain procedures for the use and removal of the manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the gloves's quality (21 CFR 820.70(h).

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## INTRODUCTION

We recommend that you conduct biocompatibility testing as described in the guidance entitled, "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," available at http://www.fda.gov/cdrh/g951.html on finished gloves. You should select biocompatibility tests appropriate for both surface and external communicating devices with limited duration (24 hours) of contact. Because medical gloves are in direct contact with skin, a primary skin irritation study and a dermal sensitization study are appropriate.

You should perform biocompatibility tests on finished gloves. The gloves used for biocompatibility studies should contain the same colorants, fragrances, flavors, powders, lubricants, and processing chemicals. You should test gloves that have been processed, packaged, and if appropriate, sterilized by the same methods as the gloves you will distribute. You should consider the need to repeat biocompatibility studies if you make subsequent changes in glove composition, manufacturing materials, or processing.

The 510(k) submission should include biocompatibility test results and other information and data described in this manual as an attached report for each major study or test program. You should identify all reports or attachments with the manufacturer's name, number the pages, and list the reports or attachments in the table of contents. For sterile devices, test data should include the results of tests performed using the finished sterilized devices.

You and the contract laboratory, if used, should check the:

- logical presentation of the biocompatibility data,
- scientific soundness of the test method and data analysis,
- relevance of the test program to the device and the intended use, and
- completeness of the summary report of the tests or studies.

We recommend that you present the summary of test results in a table format in each report whenever possible. Each study or test attachment report should contain sufficient and well-organized information in reasonable detail so that the FDA reviewer can determine:

- what exact material or device was tested,
- what tests were performed,
- how the tests were performed, and
- what were the test results.

We recommend that you submit reasonable and sufficient details of all test procedures and results to FDA. For biocompatibility studies, you should use a standard scoring system for each test method, if a standard scoring system exists. We recommend each test report include the following:

- name and address of the manufacturer of the item tested,
- name and technical description of the item tested,
- name and address of the laboratory where the tests were conducted,
- test methods, including the scoring method,
- number of samples and replicates tested,
- control data needed to establish the validity of the test,
- date when the tests were conducted,
- summary report(s) of results obtained, and
- analysis, interpretation of results, and conclusions.

You should keep the original records of the study on file. For surgeon's gloves, the records should be maintained as part of your design verification records in the design history file. You should also maintain the original records when a study, such as a biocompatibility study, is conducted by a contract laboratory to establish a device specification and/or to obtain data for a submission to FDA. The original document should include the name and address of the laboratory and device manufacturer, the device identity, and dates of testing. You should not submit the original records to FDA. During factory inspections, FDA investigators may ask to see these original records.

## SKIN IRRITATION AND DERMAL SENSITIZATION STUDIES

The following is a general discussion of how to conduct the skin irritation and dermal sensitization studies. Because methods may vary from laboratory to laboratory, the test data you submit to FDA should contain a brief description of the test protocol, scoring criteria used, and the method used for rating skin responses.

### Primary Skin Irritation Test (Animal Study)

Performing skin irritation testing demonstrates the irritation potential of the gloves, i.e., for initiating or aggravating damage through its contact with the skin. We recommend that you perform the primary skin irritation testing according to the regulations of the Consumer Product Safety Commission (16 CFR 1500.41). We recommend that you identify the inside and outside of the gloves so that both sides are tested, i.e., approximately half of the test articles expose opposite sides of the glove to the subject.

**Dermal Sensitization Study (Animal Study)**
The purpose of performing dermal sensitization is to demonstrate the potential of the device for eliciting a delayed hypersensitivity (Type IV) immunologic response through its contact with the skin. This reaction is due primarily to substances which could leach out of a material. Guinea pigs are used because they have been shown to be the best animal model for human allergic contact dermatitis. We recommend the method described in ASTM standard F720-86, Standard Practice for Testing Guinea Pigs for Contact Allergens, Guinea Pig Maximization Test, for the study. Laboratories may also use the method of Buehler, as reported in *Archives of Dermatology* (1965). Dermal sensitization studies use two tests or phases: the induction phase and challenge phase. You should identify the inside and outside of the gloves so that both sides are tested, i.e., approximately half of the test articles expose opposite sides of the glove to the subject.

**Testing for Skin Sensitization to Chemicals**
Your labeling may include special claims regarding reduced potential chemical sensitization in a 510(k), such as:

- reduced potential for sensitizing users to rubber chemical additives or,
- reduced potential for causing reaction in individuals sensitized to rubber chemical additives.

You should support these claims by data from human testing. Additional guidance on testing for skin sensitization to chemicals in latex products is available in the following guidance document:

> Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products
> http://www.fda.gov/cdrh/ode/944.html

If you have already conducted a Modified Draize Test (MDT) on a minimum of 200 human subjects to support a reduced sensitization claim, you may use the MDT data instead of the primary skin irritation test (animal) and dermal sensitization study (animal) typically used to support the general biocompatibility of medical gloves.

## COLOR AND FLAVOR ADDITIVES

You should show that any substance added to the gloves, including color, flavor, and/or scent additives, does not adversely affect the safety or effectiveness of the gloves. Therefore, if a device contains a color or other chemical additive and the device is intended to be in contact with the skin or other parts of the body, you should submit biocompatibility data to demonstrate the safety of the additives, unless you can establish that the additives would not leach and contact the body.

FDA considers the addition of color, flavor, or any chemical to a medical glove to be a significant change that should have a new 510(k) submission (21 CFR 807.81(a)(3)). You

should provide full characterization and chemical identity of the color, flavor, or scent additives. You may submit a 510(k) submission for a modification to an existing glove as a "Special 510(k)." Additional information about Special 510(k) submissions is available at http://www.fda.gov/cdrh/devadvice/3144.html.

You can find color additive and flavor additive regulations in 21 CFR parts 70 to 82 and 21 CFR part 172, Subpart F, respectively. Note that color and flavor additives contained in these regulations are specific to foods, drugs, and cosmetics. The color additive regulations should not be confused with the general 510(k) requirements, which are independent of the color additive listing and certification mentioned above. You should show that any color or flavor substance added to a device does not adversely affect the safety or effectiveness of the device. Gloves that contain FDA-approved color or flavor additives for foods, drugs, or cosmetics should undergo biocompatibility testing to demonstrate the safety of the additives in the device. We may accept other color or flavor additives not contained in these regulations with appropriate biocompatibility testing.

Medical device labeling requirements do not require the glove box or carton to have an "ingredient statement" listing the flavor agent, colorant, or other additives used in the manufacture of the glove. However, manufacturers may do so voluntarily.

See Chapter 4 for labeling considerations for medical gloves with color and flavor additives.

## LAB DIRECTORY

The websites below may be helpful in finding a testing laboratory. FDA does not certify testing laboratories. As with any supplier of services, you should verify the adequacy of the services offered (21 CFR 820.50(a)).

**The American Association for Laboratory Accreditation**
http://www.a2la2.net/

**American Council for Independent Laboratories**
http://www.acil.org/

**ASTM International**
http://www.astm.org/LABS/

**Canon Communications**
http://www.devicelink.com/consult/BiocompatibilityToxicology.html
http://www.devicelink.com/company98/category/Testing_Equipment_and_Services/index.html

**Findtesting.com**
http://www.findtesting.com/directory/category.asp?category=biological&page=7

**Thomas Register**
http://www.thomasnet.com
Search categories include:
Testing Services: Safety
Testing Services: Latex
Testing Services: Medical Equipment
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International Testing & Compliance Services
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# 4 LABELING

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## BASIC LABELING

You can find general labeling requirements for all medical devices in 21 CFR part 801. Specific labeling requirements for devices made from natural rubber latex are provided in 21 CFR 801.437.

### Name and Place of Business

- The label of a glove should contain the name and place of business of the manufacturer, packer, or distributor, including the street, address, city, state, and zip code. If the street address of the identified manufacturer, packer, or distributor is in the local (U.S.) telephone directory, you can omit the street address. (21 CFR 801.1(a) and (d)).
- If the firm identified on the label is not the manufacturer, then you should qualify the firm's name by an appropriate statement such as, "Manufactured for..." or "Distributed by...." (21 CFR 801.1(c)).

### Country of Origin

The label must contain the country of origin if other than the U.S. (19 CFR 134.11). The U.S. Customs and Border Protection enforces this regulation.

### Statement of Identity (21 CFR 801.61)

- The statement of identity of the glove must be on the principal display panel. The "principal display panel," means "…the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale." (21 CFR 801.60).

- If the glove is made of a synthetic polymer, the statement of identity should include the common, generic, or scientific name of the polymer used. The term "synthetic"

used alone does not fully characterize the composition of the glove and may mislead the purchaser. If you manufacture the glove from a blend of polymers, you should identify each component, including any blend containing natural rubber latex.

- The identity statement must list the common name of the device (21 CFR 801.61(b)). Examples include powdered latex surgeon's gloves, powdered latex patient examination gloves, powder-free latex surgeon's gloves, powder-free latex patient examination gloves, latex finger cots, powdered nitrile examination gloves, and powder-free vinyl examination gloves. You should not use undefined terms such as "low-powder."

- The identity statement must be in bold face type, reasonably related in size to the most prominent printed matter on the display panel, and in lines generally parallel to the base of the package when rested (21 CFR 801.61(c)).

**Language**

All labeling must be in English with the exception of those products distributed solely within Puerto Rico or a U.S. Territory where the predominant language is not English (21 CFR 801.15(c)(1)). If any representation on the device label or labeling appears in a foreign language, then all required labeling must also appear in that foreign language (21 CFR 801.15(c)(3)).

**Net Quantity of Contents Statement**

The label must contain a statement of net quantity of contents in terms of weight, measure, numerical count, or statements of both numerical count and weight, measure, or size (21 CFR 801.62(a)). Whichever statement of net quantity of contents you use, you should state it clearly and understandably on the label, e.g., "100 gloves, packaged by weight."

The net quantity declaration must appear as a separate item in the lower 30 percent of each principal display panel. You must separate it, by at least a space equal to the height of the lettering used in the declaration, from other information appearing above and below. Also, you must separate the declaration by at least twice the width of the letter "N" from labeling to the left or right. (21 CFR 801.62(e)).

**Adequate Directions for Use**

You should label disposable medical gloves as "single use only." The label for surgeon's gloves should contain any necessary directions for use.

## DEVICES THAT CONTAIN NATURAL RUBBER

**Caution Statement.** If your medical gloves contain natural rubber latex, you must put the following statement in bold print on the device labeling:

**"Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."**

This statement must appear on all device labels, and other labeling, as well as on the principal display panel of the device packaging, the outside package, container, or wrapper, and the immediate device package, container, or wrapper (21 CFR 801.437(d)).

## EXPIRATION DATE LABELING

Expiration date labeling for medical gloves is voluntary. However, if you make an expiration date labeling claim, the gloves should meet the performance characteristics and specifications presented in the Premarket Notification (510(k)) over the entire claimed shelf life. Manufacturers with cleared 510(k) submissions for surgeon's or patient examination gloves do not have to submit new 510(k) submissions to add an expiration date to the labeling.

You should perform real-time stability studies in order to determine an expiration date. The stability studies should include tests to verify that medical gloves maintain their barrier properties, physical properties, packaging integrity, sterility, and any specific attributes claimed in the labeling over the entire shelf life of the glove. We recommend the following tests:

- **Barrier property tests.** You should perform the FDA 1000 mL Water Leak Test (21 CFR 800.20) or ASTM International (ASTM) D5151, Standard Test Method for Detection of Holes in Medical Gloves to assess barrier integrity.

- **Physical properties tests.** You should use appropriate physical properties tests such as those in ASTM D3577, Standard Specification for Rubber Surgical Gloves; ASTM D3578, Standard Specification for Rubber Examination Gloves; ASTM D5250, Standard Specification for Poly (vinyl chloride) Gloves for Medical Application; ASTM D6319, Standard Specification for Nitrile Examination Gloves for Medical Application; or an equivalent appropriate physical property test.

- **Sterility and package integrity tests.** You should test sterile glove packaging for package integrity and the ability to maintain sterility. Documentation should include evidence that, after storage, the product packaging still meets the manufacturer's specifications for package integrity.

- **Tests to support labeling claims**. You should test for properties that may be adversely affected by product aging, such as resistance to chemicals. Manufacturers should document this testing.

Manufacturers/sponsors may use test protocols from the applicable voluntary consensus standards or may develop their own protocols for stability testing. If you develop original protocols, you should describe the protocols in detail (test methodology, acceptance criteria,

time intervals for testing). You should give a rationale for any variation from the applicable consensus standard. Manufacturers should maintain the originals of all protocols, test reports, and identification of persons/labs performing the test at their manufacturing establishment so that the information is available for review during an FDA inspection.

**Provisional Expiration Date**

FDA will accept a provisional expiration date of up to 3 years from the date of manufacture based on accelerated aging studies, provided the manufacturer immediately initiates real-time stability testing to obtain data to support the proposed expiration date. You should perform accelerated aging studies at a minimum of two elevated temperatures between 40 and 80 degrees C°. If the product does not meet the required criteria after accelerated aging, you should label the product with a shelf life determined by real-time testing. FDA believes that expiration dates based on real time data should not exceed 5 years from the date of manufacture. If the real-time data do not support the expiration date based on accelerated aging, you should change the expiration date to reflect actual shelf life.

**Test Reports**

We recommend that you generate test reports to document both the real-time and accelerated aging of the gloves. Test report documentation should be consistent with the appropriate standards. In addition, we recommend that each test report should include the following information:

- product identification, including lot numbers and date of manufacture
- test method identification, including documentation for in-house procedures
- sample size and acceptance criteria for each test conducted
- description of product packaging during storage (e.g., individually packaged, standard sterile packaging)
- description of storage environment (temperature and humidity) and duration of storage
- time elapsed between date of manufacture and each testing interval
- raw test data, including an appropriate statistical summary
- data analysis
- conclusion, including the shelf life supported by the data.

**Labeling**

When you establish the shelf life of the gloves using real time stability testing, or when you establish a provisional shelf life using accelerated aging, the expiration date labeling on medical gloves should conform with the following:

1. You can obtain the expiration date for a specific lot of gloves by adding the established shelf life to the date of manufacture for that lot. The "date of manufacture" refers to the date of completion of the final step of the manufacturing process (final packaging or sterilization).

2. The expiration date should state the month and year of the shelf life. You should express the expiration date by spelling out the name of the month followed by the 4-digit year, e.g., January 2006. You should not express the date as 1/10/06 because this may be interpreted as October 1, 2006, in some parts of the world, resulting in the use of outdated and degraded gloves.

3. The expiration date, stated as "Use Before: [date]" should be prominently displayed on the exterior of the primary and retail package and on the shipping carton.

4. Sterile surgeon's and patient examination gloves that have an expiration date based on sterility that is different from the expiration date based upon physical and mechanical integrity testing should bear only the earlier expiration date.

ASTM International developed the following standards for expiration dating of medical gloves:

- D7160-05 Standard Practice for Determination of Expiration Dating for Medical Gloves
- D7161-05 Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions

You can obtain more information on these standards directly from ASTM at http://www.astm.org.

## DONNING POWDER OR LUBRICANT IDENTIFICATION

If surgeon's gloves are powdered, they must be powdered with an absorbable dusting powder that has received FDA approval under either an NDA or a PMA (21 CFR 878.4480). The labeling should inform users with a statement such as, **"**Powdered with absorbable dusting powder." Absorbable powder for lubricating a surgeon's glove is a Class III medical device under 21 CFR 878.4480. For more information about glove lubricants, see Chapter 2 of this manual.

If patient examination gloves are powdered, the powder should meet the United States Pharmacopoeia (U.S.P.) monograph for absorbable dusting powder or demonstrate equivalence in terms of safety and effectiveness. U.S.P powder is commonly used on examination gloves so the corresponding labeling statement should read, **"**Powdered with absorbable dusting powder, U.S.P."

## ATTRIBUTE LABELING

In addition to basic labeling described above, manufacturers may have labeling claims for the attributes of their gloves. Some attributes are color, flavor, scent, and thickness. You should

submit data to support all claims in your 510(k). You should not use ambiguous labeling claims such as "extra thick" or "super-sensitive" because they are misleading. You should use acceptable factual and definitive statements, such as the actual glove thickness as determined by measurement.

Section 502 of the Act prohibits labeling that is false or misleading in any way (21 U.S.C. 352). Any labeling claim should describe the device truthfully and accurately. See Chapter 9, Compliance Activities, for more information on labeling.

**"Powder-Free"**

Gloves with trace amounts of residual former-release powder (2 mg or less per glove) and no intentionally added donning powders are commonly referred to as "powder free." Most manufacturers dip the glove mold, known as a "former," into a solution of calcium carbonate and calcium nitrate. After controlled drying, manufacturers dip the coated former into the latex solution and create a glove on the former. The calcium carbonate helps release the glove from the former. An extremely small amount of calcium carbonate remains on the glove. Most of it is removed by leaching and washing.

FDA has recognized standard method ASTM D6124, Standard Test Method for Residual Powder on Medical Gloves, for collecting and measuring the manufacturing debris, residual former-release powder, and other elements on a powder-free glove or the powder levels on powdered medical gloves.

To establish a "powder-free" claim, FDA recommends that you have no more than 2 mg of residual or trace powder and debris per glove, as determined by the ASTM D6124 test method (Standard Test Method for Residual Powder on Medical Gloves) or an equivalent method.

**Protein Label Claims**

Latex proteins can cause Type I sensitivity in some individuals who have been exposed to latex-containing devices. Repeated exposure to latex proteins may increase the probability that an individual will become sensitized. Since May 1991, the FDA has recommended that manufacturers of latex devices reduce the water-extractable protein on their natural rubber latex devices. FDA considers water soluble latex proteins to be concomitant constituents, which are manufacturing materials under the Quality System regulation, 21 CFR 820.3(p). FDA requires the reduction of these types of materials according to 21 CFR 820.70(h).

Manufacturers who can reliably reduce the levels of latex proteins in their gloves to a known level may make a labeling claim, if they submit supporting data in their 510(k) submission. At present, FDA does not allow a protein labeling statement or claim below the current 50µg/$dm^2$ sensitivity limit of the ASTM Lowry test method (D5712). Work is being done to determine the sensitivity and detection limits of the ELISA test method (ASTM D6499). At the time of this writing, these limits are unknown.

FDA suggests that you measure the natural rubber latex protein on recently manufactured finished gloves that have undergone accelerated aging according to the ASTM standard D3578 (Standard Specification for Rubber Examination Gloves) or D3577 (Standard Specification for Rubber Surgical Gloves) or real time aging. Water soluble proteins may migrate to the glove surface during shipping. Aging should approximate this time period.

If you label your gloves as containing 50µg/dm$^2$ or less per glove of extractable protein, the labeling should also state:

> "Caution: Safe use of these gloves by latex sensitized individuals has not been established."

You must ensure that any labeling changes to dispenser boxes and any changes to manufacturing processes meet the requirements of the Quality Systems regulation in 21 CFR 820.30 (for surgeon's gloves), 820.40 and 820.70. See Chapter 8, Quality System, for further guidance.

**Chemical Sensitization**

Certain chemicals routinely used in the manufacture of medical gloves, such as natural rubber latex and other materials, can cause skin sensitization and irritation. If you sufficiently reduce or eliminate the presence of these chemicals, you may make appropriate labeling claims regarding the reduced potential of chemical sensitization or reduced reaction-inducing potential of your gloves in allergic individuals if cleared in a 510(k) submission. You can find guidance about reduced sensitization claims for latex gloves in the guidance document "Premarket Notification (510(k)) Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products" at http://www.fda.gov/cdrh/ode/944.html. Refer to Chapter 3, Biocompatibility, for additional information on biocompatibility.

**Color and Flavor Additives**

Medical device labeling does not require an "ingredients statement" listing the flavor agents or colorants used in the manufacture of the gloves on the glove box or carton. However, manufacturers may do so voluntarily.

FDA considers the addition of colorants, other than traditional whiteners, such as titanium dioxide or the addition of a flavoring agent to a medical glove, to be a significant change which should have 510(k) clearance (21 CFR 807.81(a)(3)). The new finished glove should undergo full biocompatibility testing.

**Chemotherapy Label Claim**

Medical gloves with a chemotherapy claim should meet an appropriate FDA-recognized consensus standard for medical gloves or an equivalent test method. Physical features such as increased thickness and length make these gloves more suitable for the safe handling of chemotherapy agents (usually minimal thickness of 0.10 mm, minimal length of 270 mm).

Gloves for use with chemotherapy agents should also undergo the standard biocompatibility testing for medical gloves.

To market the glove for use in the handling and/or preparation of chemotherapeutic drugs, you should label the glove as a "Patient Examination Glove" or "Surgeon's Glove" and "Tested for use with [name of chemotherapeutic drug(s)]."

We recommend that you include the following labeling information (to enable the user to make an appropriate product selection):

- chemical resistance data (test method used, chemicals tested), for consumer review, if desired,

- the statement, "Gloves used for protection against chemotherapy drug exposure should be selected specifically for the type of chemicals used," and

- instructions for users to review drug labeling or material safety data sheets for the chemicals being used to determine an adequate level of protection for the intended use.

**Pyrogen/Endotoxin Labeling Claim**

FDA may consider a non-pyrogenic claim on a case-by-case basis for surgeon's gloves. The 510(k) submission should contain data to support the claim. In addition, the Quality System regulation includes requirements for, but not limited to, design controls, process validation, and process controls (21 CFR part 820). If you label your glove as non-pyrogenic, you should design the glove and validate the manufacturing process from the onset of manufacture to the finished packaged device. You should continuously monitor the bioburden throughout the entire process to assure the bioburden is within the validated specifications. The bioburden monitoring should include the slurry tank for the glove powder used to lubricate the gloves, as well as any bacterial over-growth that may occur subsequent to powdering and prior to sterilization. You should establish manufacturing timeframes to minimize growth at every stage of the process.

**Hypoallergenicity**

For medical gloves distributed after September 30, 1998, 21 CFR 801.437(h) states "Devices that contain natural rubber that contacts humans...shall not contain the term 'hypoallergenic' on their labeling." This includes gloves that have received prior 510(k) marketing clearance with a claim of hypoallergenicity. Hypoallergenic incorrectly implies that latex sensitive persons may use a product labeled as "hypoallergenic" safely.

FDA strongly discourages the use of the term "hypoallergenic" because the term cannot be scientifically defined or quantified. Because there is virtually no way to rule out allergies to any substance, FDA strongly discourages using the term "hypoallergenic" regarding any medical device, whether the device contains natural rubber latex or not.

FDA does not require a new 510(k) submission for labeling changes made to comply with 21 CFR 801.437, provided that you do not make any other changes requiring a new 510(k) submission. However, you should keep appropriate records documenting the labeling changes.

## STANDARDS

For voluntary labeling claims, you may state in the labeling that the product meets specific national or international consensus standard(s). The labeling should clearly identify the standard by name or alphanumeric text, including the year published or other information to identify the specific standard. If you make a voluntary claim, it should be truthful and accurate. Note that a 510(k) submission may contain a declaration of conformity with any or all parts of a standard without an associated claim in the labeling.

If the label states that a product meets a specific standard, the product delivered to the customer should meet the standard. The manufacturer should have data on file to support these claims.

## LOT NUMBER

Although FDA does not require a lot number to be placed on glove packaging, it is industry practice for the package of medical gloves to bear a lot number. Lot numbers are useful for traceability for complaints or returned product. This number or code may identify the batch of compounded latex, the production lines, the production shift, and/or, if sterile, the sterilization run. Some international consensus standards require lot numbers for conformance. Gloves conforming to those standards should have lot numbers. The lot number should be visible on the outside of the immediate packaging.

## BAR CODING

Many manufacturers have started placing bar codes on cartons and on the bottom of dispenser boxes. FDA encourages the use of bar coding.

**EXAMPLE LABELING**

The following are examples and do not represent real products:

**Example: Powdered Latex Patient Examination Glove Box, Top**

# ABC® BRAND
# POWDERED LATEX EXAMINATION GLOVES

Powdered with absorbable dusting powder, U.S.P.

**Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**

Single Use Only
Nonsterile



**Distributed by:**
**ABC Corporation**
**Boston, MA 10001**
**Lot # 03C2004**

**CONTENTS: 100 Gloves (by weight)**
**SIZE: MEDIUM**

**Example: Powdered Latex Patient Examination Glove Box, Side**

## ABC® BRAND
## POWDERED LATEX EXAMINATION GLOVES

CONTENTS: 100 Gloves (by weight) SIZE: MEDIUM
Powdered with absorbable dusting powder, U.S.P.
Single Use Only

Distributed by:
ABC Corporation
Boston, MA 10001

Product of Malaysia

Lot: 03C2004

**Example: Powder-Free Latex Patient Examination Glove Box, Top**

# ABC® BRAND
# POWDER-FREE LATEX EXAMINATION GLOVES

**Lubricated with Silicone**

**Single Use Only**

**Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**



**Manufactured For:**
**DSMICARES Inc.**
**Rockville, MD 20850 USA**

**CONTENTS: 100 Gloves (by weight)**
**SIZE: MEDIUM**

**Example: Powder-Free Patient Examination Glove Box, Side (**with voluntary expiration date and lot number)

# ABC® BRAND
# POWDER-FREE LATEX EXAMINATION GLOVES

**Lubricated with Silicone**
**Single Use Only**
CONTENTS: 100 Gloves (by weight)
SIZE: MEDIUM
Manufactured For:
DSMICARES Inc. Use Before: Dec. 2006
Rockville, MD 20850 USA Product of Thailand Lot: 051199

**Example: Powdered Vinyl Patient Examination Glove Box, Top**

# ABC® BRAND
# POWDERED VINYL EXAMINATION GLOVES

**Powdered with absorbable dusting powder, U.S.P.**
**Single Use Only**



**CONTENTS: 100 Gloves (by weight)**
**SIZE: MEDIUM**

**Manufactured For:**
**Medical Art, Inc.**
**Terrell, MD 28888 USA**

**Example: Powdered Vinyl Patient Examination Glove Box, Side**

# ABC® BRAND
# POWDERED VINYL EXAMINATION GLOVES

CONTENTS: 100 Gloves (by weight) SIZE: MEDIUM

Single Use Only
Powdered with absorbable dusting powder, U.S.P.

Manufactured For:
Medical Art, Inc.
Terrell, MD 28888 USA Product of Taiwan Lot: 031100

**Example: Powdered Surgical Glove Unit Package**

↓↓ **PEEL DOWN TO OPEN** ↓↓

# ABC® BRAND

# STERILE

# POWDERED LATEX SURGICAL GLOVES

**Single Use Only**
**Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**

**CONTENTS: One Pair (2 Gloves)**

SIZE: 7

**Powdered with absorbable dusting powder**

Do NOT use if packaging is damaged.

Lot: S101000 Use Before: November 2006

Distributed by:
ABC Corporation
Big Apple, NY 10018 Product of Indonesia

# 5 PREMARKET NOTIFICATION 510(K)

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## INTRODUCTION

A Premarket Notification (510(k)) is a submission of information sent to the FDA to obtain marketing clearance for a medical device. A 510(k) submission is a comparison of a new device with a "predicate" device. A predicate device is a legally marketed device to which equivalence is established. The 510(k) documents that the new finished medical glove you wish to market is as safe and effective as a legally marketed medical glove in the U.S. You cannot market medical gloves in the U.S. until you receive a letter from FDA declaring the gloves substantially equivalent (21 CFR 807.100(a)(5)).

ASTM International (ASTM) has developed a number of medical glove related standards. CDRH has officially recognized many of these standards for premarket clearance purposes. Conformance to these standards is voluntary. (See Chapter 10 of this guidance for more information on voluntary standards.)

You should provide physical parameter and biocompatibility data obtained from tests and inspection of packaged and sterilized gloves (finished gloves). The 510(k) submitter should keep this documentation on file.

You can find detailed instructions for a 510(k) submission for patient examination gloves and surgeon's gloves in Chapters 6 and 7, respectively.

## TYPES OF 510(k) SUBMISSIONS

A 510(k) submitter may choose from three types of Premarket Notification 510(k) submissions for marketing clearance: Traditional, Special, and Abbreviated. The traditional 510(k) method is the original submission as provided in 21 CFR part 807. There are two optional alternatives to the Traditional 510(k) method for obtaining 510(k) marketing clearance under certain instances: Special 510(k) and Abbreviated 510(k). The Special

510(k) Device Modification utilizes certain aspects of the Quality System regulation to streamline 510(k) review; the Abbreviated 510(k) relies on the use of guidance documents, special controls (for class II devices), and recognized standards to facilitate 510(k) review. Additional information about the 510(k) submission process is available at http://www.fda.gov/cdrh/devadvice/314.html.

**510(k) FEE**

As of October 1, 2002, FDA charges a fee to review 510(k) submissions. This submission fee applies to Traditional, Abbreviated, and Special 510(k)s. FDA should receive payment on or before the time you submit the 510(k) submission. If the submitter has not paid all fees owed, FDA will consider the submission incomplete and will not accept it for filing. You should direct questions regarding user fees to the Division of Small Manufacturers, International and Consumer Assistance at 240-276-3150.

Additional information, including the current review fee for a 510(k), is available at http://www.fda.gov/cdrh/devadvice/314a.html.

**INDICATIONS FOR USE STATEMENT**

For medical gloves, the indication for use is the same as the intended use. The information, data, and labeling claims in the entire 510(k) submission should support and agree with the Indications for Use statement. CDRH will attach the Indications for Use statement to the substantial equivalence letter that is sent to the submitter when the 510(k) is cleared.

We recommend one of the following statements or equivalent text as an indication for use statement.

**Powdered Examination Gloves**
A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

**Powder-Free Examination Gloves**
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

**Powdered surgeon's gloves**
A powdered surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

**Powder-free surgeon's gloves**
A powder-free surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

For a special purpose glove, you should include additional text in the Indications for Use statement that covers the additional function of the glove as stated in your labeling. You should also indicate that it is an over-the-counter device.

## LABELING

Medical glove 510(k) submissions should include samples of the package labeling. Labeling does not need to be in final printed format; you may submit draft labeling. The final labeling should be consistent with the draft labeling you submitted in the 510(k). The final labeling should agree with your drawings for labeling and preprinted packaging in your Quality System device master record (21 CFR 820.181), and comply with other applicable requirements in the Act and regulations.

Labeling, labeling claims, and data should be consistent with the Indications for Use statement. If you make any specific claims for your gloves, you should include data to substantiate the claims in this format or in identified attachments. Puffery, ambiguous, or unsubstantiated claims such as super strong, extra thick, micro thin, super sensitive, or low protein, are not appropriate.

## POWDER FOR EXAMINATION GLOVES

Powder used for lubricating examination gloves should meet the United States Pharmacopoeia (U.S.P.) monograph for absorbable dusting powder or be equivalent in terms of safety and effectiveness. The 510(k) should include the type, specifications, and source of powder or other donning lubricant used on the gloves. You should not use talc, cotton flock, and other non-absorbable materials as a lubricating, dusting, or donning powder. Lycopodium (club moss spores) and ground pine pollen are toxic and are not acceptable as powder on or in medical gloves.

## POWDER FOR SURGEON'S GLOVES

Absorbable donning or dusting powder from powder manufacturers that have obtained an approved new drug application (NDA), abbreviated new drug application (ANDA), or premarket approval application (PMA) must be used on powdered surgeon's gloves (21 CFR 878.4480). A list of firms with approved NDAs or PMAs for Surgical Dusting Powder is available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Use Product Code "KGP" as the search term.

## COATINGS

Premarket Notification 510(k) submissions for coated medical gloves should contain complete information about the composition and intended purpose of the coating used, e.g., ease of donning. The draft labeling should also contain any special or additional claims for the gloves due to the presence of the coating, e.g., "easier to don."

## STERILITY

For gloves that are labeled as sterile, FDA recommends that you provide sterilization information in accordance with "Updated 510(k) Sterility Review Guidance K90-1" available at http://www.fda.gov/cdrh/ode/guidance/361.html. You should sterilize the gloves to a sterility assurance level (SAL) of $1 \times 10^{-6}$ using a sterilization cycle that has been validated in accordance with the Quality Systems requirements, 21 CFR part 820.

## 510(k) SUMMARY OR STATEMENT

In accordance with 21 CFR 807.87(h), the Premarket Notification 510(k) submission must include either a 510(k) Summary or a 510(k) Statement:

> 510(k) Summary is a summary of the 510(k) in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence (21 CFR 807.92).
>
> 510(k) Statement is a certification that the 510(k) holder will provide a copy of the entire 510(k) submission, excluding patient identifiers, trade secret, and confidential commercial information, to any person within 30 days of a written request (21 CFR 807.93). You may not charge requesters for a copy of the 510(k) submission..

You should make the choice between the 510(k) Summary and 510(k) Statement before you submit the 510(k). You may elect to change your choice between the summary or statement before FDA determines substantial equivalence. FDA will accept Summaries or amendments to Summaries until FDA issues a determination of substantial equivalence. After the determination, you cannot modify the 510(k) Summary or change your choice of a 510(k) Summary or 510(k) Statement. See 21 CFR 807.92(a).

Further information regarding the content of the 510(k) Summary or 510(k) Statement may be obtained at www.fda.gov/cdrh/devadvice/314312.html#link_7.

### 510(k) Summary

We provide the following supplemental information for 510(k) Summaries for medical gloves.

21 CFR 807.92(a)(2)
Examples:
Trade name - ABC® Latex Examination Gloves
Common name - exam gloves
Classification name - patient examination glove

21 CFR 807.92(a)(4)
You should describe any variations from the predicate device. For special purpose gloves, describe the special features.

21 CFR 807.92(a)(6)
We recommend that you include a brief table of the measured parameters of your finished gloves compared to FDA-recognized consensus standards or equivalent methods. You should include data that show conformance with FDA biocompatibility, pinhole, powder residual and other specifications and recommendations and any other parameter for which you have a labeling claim.

21 CFR 807.92(b)(2)
Clinical data is usually not needed for medical glove 510(k) submissions.

21 CFR 807.92(b)(3)
We recommend that you state that your gloves meet the FDA-recognized consensus standard or equivalent method and meet your labeling claims and pinhole acceptable quality level (AQL) as shown by the data in 21 CFR 807.92(a)(6).

**510(k) Statement**

The statement should be on a separate letterhead page, clearly identified as "510(k) statement," signed by the certifier, not a consultant to the 510(k) submitter, and should include the specific language provided in 21 CFR 807.93.

Premarket Notification 510(k) Statement
http://www.fda.gov/cdrh/manual/stmnt2.html

## PRODUCT MODIFICATIONS

If you make a change to your gloves that significantly affects safety or effectiveness of the gloves, you must submit a new and complete 510(k) (21 CFR 807.81(a)(3)). Examples of changes that may require a new 510(k) include adding or deleting powder; adding color, fragrance, or a claim to the labeling; or modifying an important process. FDA usually does not require a new 510(k) if a manufacturer only does more of an existing process, such as extra leaching or washing, and makes no claim or mention of this change on the product labeling.

Changes to patient examination gloves, labeling, packaging, and processes should meet the Quality System regulation at 21 CFR 820.40 and 820.70(b). You should make changes to surgeon's gloves, labeling, packaging, and processes in accordance with Quality System regulation at 21 CFR 820.30, 820.40, and 820.70(b). If you do not need a new 510(k), you should document your decision and how you arrived at it in the device master record (21 CFR 820.181).

We recommend the following guidance document for additional information:

> Deciding When to Submit a 510(k) for a Change to an Existing Device
> http://www.fda.gov/cdrh/ode/510kmod.html

You may submit a "Special" 510(k) submission for a modification to an existing glove 510(k) held by the same submitter.

**TRANSFER OF OWNERSHIP OF A 510(k)**

A 510(k) may be bought, sold, or transferred. FDA is not involved in transfers of ownership. The new owner should maintain information documenting the transfer of ownership of a 510(k), including any legal transactions that took place, in its 510(k) files.

The new owner should list the device according to 21 CFR part 807 and the previous owner should delete its device listing. Upon inspection of the firm or upon entry of glove shipments into the U.S., FDA may request a review of documentation of ownership. If the owner is not able to provide the information, FDA may request the owner to submit a 510(k). You may not distribute the gloves until FDA clears the new submission.

Note that neither a registration nor a listing proves 510(k) ownership. The new owner of the 510(k) should maintain files with documentation proving ownership of the 510(k).

To avoid problems when importing a device with a transferred 510(k) ownership, FDA recommends that a copy of the specific information relating to the ownership sale or transfer accompany all shipments to the United States. This could be a simple one-page document detailing the transfer transaction.

# 6 PATIENT EXAMINATION GLOVES

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## POWDER-FREE

To substantiate a “powder-free” claim in your Premarket Notification (510(k)) submission, you should state whether the manufacturing process for the glove includes any powder, such as a former-release powder and/or a donning powder. If it does, you should provide:

1. a description of the powder(s) introduced at any stage of the glove manufacturing process, such as former release or stripping powder and donning powder;

2. a detailed description of the process to remove the added powder(s);

3. a description of the release specification supporting the powder-free claim and a brief summary of the final product testing to ensure the glove meets this specification;

4. a description of how the glove is designed or manufactured to compensate for the lack of donning powder, or reasons why the compensation is not necessary, including a full characterization such as the chemical identity, specifications, and biocompatibility of any material such as silicone added to the glove to facilitate glove donning; and

5. a certification that the finished powder-free glove meets ASTM International (ASTM) standard D3577 (Standard Specification for Rubber Surgical Gloves), D3578 (Standard Specification for Rubber Examination Gloves), D5250 (Standard Specification for Poly(vinyl chloride) Gloves for Medical Application), or an equivalent standard, as appropriate.

If the entire manufacturing process does not include any former release or donning powder, then you only need to discuss items 4 and 5 in the above list.

## CHEMOTHERAPY GLOVES

Chemotherapy gloves are specialty medical gloves. We recommend that you use the 510(k) format for chemotherapy gloves provided later in this chapter. If you label patient examination gloves designed for handling chemotherapy agents as, “Tested for Use with Chemotherapy Agents," you should provide data to support the claim. Otherwise, labeling, donning powder or lubricant, protein, and powder-free specifications for chemotherapy gloves are the same as for examination gloves.

You should include in the 510(k) submission the results of a controlled scientific study completed on the finished device to substantiate the claim. Test data should show the gloves are chemically resistant and/or can resist the permeation of chemical agents. Chemical resistance includes resistance of the glove to swelling, degradation, or deformation. The test method for permeability determines the time for a hazardous liquid (including temperature and concentration, if necessary) to permeate the barrier membrane of the glove as well as the rate of penetration once the barrier has been breached.

Testing should utilize the actual chemicals to be encountered, using the finished product, under the expected in use conditions (i.e., length of exposure, chemical concentration, contact, and temperature). Supporting test data should include an explanation and/or method of selecting the chemicals tested, a comprehensive description of the test method used, the complete protocol, an analysis of test results, a discussion, and the conclusions.

Chemotherapy gloves should meet an appropriate ASTM standard or an equivalent consensus standard for medical gloves. Physical features, such as increased thickness and length, make them more suitable for the safe handling of chemotherapy agents (usually minimal thickness of 0.10 mm, minimal length of 270 mm).

Premarket Notification (510(k)) submissions for Chemotherapy gloves should contain:

- the product labeling that specifies the chemical(s) that the glove provide(s) protection against;
- the results of a controlled scientific study to substantiate the claim,
- a comprehensive description of the test method used,
- the complete test protocol,
- an analysis of test results,
- a discussion as appropriate, and
- conclusions.

Chemotherapy gloves should also undergo standard biocompatibility testing for medical gloves.

## FORMAT FOR PREMARKET NOTIFICATION 510(k)

This section contains a suggested format for the submission of a Premarket Notification (510(k)) for patient examination gloves. FDA does not require this format, but you may use it as a guide for submitting the necessary information to FDA. The suggested format should increase the completeness and accuracy of your submission and may reduce the time needed for review of your submission.

Although a single 510(k) submission for colored, flavored, or scented gloves may include more than one color and/or flavor or scent, you should test each glove type separately, as a

finished glove, for biocompatibility and all physical characteristics. Data for multiple types of gloves should be in separate attachments.

A 510(k) submission should be complete; that is, you should not reference information from a previous 510(k) submission.

We recommend that you identify all attachments with the topic and the submitter's name, street address, phone, and fax numbers. You should number the pages in your submission and attachments and include a table of contents. Do not include unnecessary information such as copies of standards and details of test equipment.

**Sample Format for a Premarket Notification 510(k) for Examination Gloves**

We recommend that you follow the Abbreviated 510(k) format provided in the guidance document, "Format for Traditional and Abbreviated 510(k)s" available at http://www.fda.gov/cdrh/ode/guidance/1567.html The guidance document will help you create a complete 510(k). Pertinent elements of a 510(k) are reiterated below and are described in the guidance.

- Medical Device User Fee Cover Sheet (Form FDA 3601). See 510(k) Review Fees at http://www.fda.gov/cdrh/devadvice/314a.html for additional information.
- CDRH Premarket Review Submission Cover Sheet available at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf or http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.doc
- Cover letter as described in the format guidance
- Table of Contents (recommended)
- Indications for Use available at http://www.fda.gov/cdrh/devadvice/314312.html#link_6
- 510(k) Summary (21 CFR 807.92) or 510(k) Statement (21 CFR 807.93). See Chapter 5 of this manual.
- Truthful and Accuracy Statement (21 CFR 807.87(k)) available at http://www.fda.gov/cdrh/manual/stmnt2.html

- Provide items required under 21 CFR 807.87 (Information required in a Premarket Notification submission). We recommend the following format for a patient examination glove 510(k) submission.

**Executive Summary:**
We recommend you that you provide an executive summary of the 510(k), which should include a concise description of the device, including the indications for use and concise summary for any performance testing in the submission. We recommend that you identify all variations (for example, various colors) of gloves covered in the 510(k) submission. If this submission is for a modification of a patient examination glove cleared by FDA for marketing, include the 510(k) number of the cleared glove.

**Classification Information:**

Device Class: Class I
Device Name: Patient examination gloves - 21 CFR 880.6250

**Product Code**

[ ] Latex - LYY
[ ] Vinyl - LYZ
[ ] Synthetic Polymer - LZA
[ ] Nitrile - LZA
[ ] Specialty - LZC
[ ] Finger Cot - LZB

If the glove is made of a polymer or other type of material. identify the material.
_____

**Device Description and Specifications** (of your specific Latex or Synthetic "xxxx" Polymer Glove):

Overall Length:_____mm minimum
Width: _____mm minimum (for medium glove)
Palm Thickness:_____mm minimum
Finger Thickness: _____mm minimum
Tensile Strength:
before aging _____ Mpa minimum
after aging _____Mpa minimum
Ultimate Elongation:
before aging _____% minimum
after aging _____ % minimum
Pinhole AQL: _____

If latex gloves:
Does the above data for your examination gloves meet all the current specifications listed under the ASTM standard D3578 or an equivalent consensus standard?

YES ___ NO ___ If NO, explain why in an identified attachment.

If vinyl:
Do the vinyl examination gloves meet all the current specifications listed under ASTM Specification D5250 or an equivalent consensus standard?

YES ___ NO ___ If NO, explain why in an identified attachment.

If synthetic polymer gloves:
Does the above data for your synthetic/polychloroprene examination glove meet all the current specifications listed under the applicable ASTM standard D3578, D6977, or a standard for gloves composed of the specific synthetic polymer/nitrile glove?

YES ___ NO ___ If NO, explain why in an identified attachment.

If nitrile gloves:
Does the above data for your nitrile examination glove meet all the current specifications listed under the applicable ASTM standard D6319 or an equivalent consensus standard?

YES ___ NO ___ If NO, explain why in an identified attachment.

**Specialty, Chemotherapy Gloves:**
For chemotherapy or other specialty gloves, include data in an identified attachment to demonstrate the gloves are safe and effective to support labeling claims. (See Chapter 4 for guidance on labeling of medical gloves intended for use with chemotherapy agents.)

**Former Release Powder or Chemical:**
(If none is used, state that no release powder or chemical is used.)

Release Powder
or Chemical: _____

Supplier : _____

Specifications: _____

**Dusting or Donning Powder:**
(If none, state "powder-free")

Note: ASTM standards do not allow talc on the surface of medical gloves. Lycopodium (club moss spores) and ground pine pollen are toxic and are not acceptable as powder on or in medical gloves.

U.S.P. Absorbable Dusting Powder used?
YES _____ NO _____

If non-U.S.P. absorbable dusting powder is used, provide the following:

Powder Type: _____

Supplier:_____

Brand Name:_____

Specifications: _____

Weight of Donning Powder:
Weight of all types of powder on finished powder glove _____ +/- ____ milligrams per $dm^2$. Powder should be measured by ASTM D6124 or an equivalent test method.

**Weight of Residual or Trace Powder Residue on "Powder-free" Gloves:**
Weight of all types of residual or trace powder on finished powder-free glove _____ +/- _____ mg per glove determined by ASTM D6124. The weight of trace powder should not exceed 2 mg per glove or the limit in the ASTM standard.

If the gloves are powder-free, and the process includes any mold/former release or donning powder, we recommend that you provide the following:

Describe the powder(s) introduced at any stage of the glove manufacturing process.

In an identified attachment, describe in detail the process to remove the added powder(s).

In an identified attachment, include and describe the finished glove release specification supporting the "powder-free" claim and a brief summary of final product testing to ensure finished gloves meet this specification. (You should use the ASTM D6124 method or an equivalent method for measuring residual or trace powder.)

If the gloves are powder-free and the manufacturing process does NOT include any powder, we recommend that you provide the following.

Describe in an identified attachment how the glove is designed or manufactured to compensate for the lack of donning powder, or reasons why compensation is not necessary, including a full chemical characterization (e.g., chemical identity, specifications, biocompatibility) of any material used to facilitate glove donning, such as silicone or polymer coating on the glove. If a donning lubricant is used, state the composition and include biocompatibility data for the lubricant in an identified attachment; also state the name, manufacturer, and address below:

Lubricant
Generic Name: _____

Lubricant
Brand Name(s): _____
Chemical Name: _____

Lubricant
Manufacturer: _____

Address: _____

_____

We recommend you certify that your finished "powder-free" gloves meet the following:

- ASTM D3578 standard or equivalent standard for natural rubber latex,
- ASTM D 5250 standard or an equivalent standard for vinyl, or
- ASTM D6319 standard or an equivalent standard for nitrile.

**Protein Level of Natural Rubber Latex Gloves:**
Protein level as measured by a standard method recognized by FDA _____ mcg/dm2.

Was a Standard Test Method used to determine the protein level?

YES _____ NO_____

Specify the Standard Test Method used,
including the year _____

If no, include a complete description of the test method used and data showing how it correlates with a recognized standard method. You may check the CDRH website for a list of currently recognized standard test methods. The searchable standards database is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

The protein testing was performed on the finished gloves that have undergone real time aging or accelerated aging per ASTM D3578:

YES _____ NO _____

We recommend that you include a summary of test results from samples of at least one lot of gloves that supports your stated protein level.

**Protein Control:**
We recommend that you specify what test will be used for determining protein content during routine production: _____.

If this is not a Standard Test method, please provide data correlating the routine quality control method to a recognized standard test method.

**Chemical Sensitivity Claim:**
If your labeling makes claims regarding the reduced potential of chemical sensitization or reduced reaction-inducing potential of your gloves in allergic individuals, you should provide supporting data in an identified attachment. We recommend the attachment present a summary of the data from appropriate testing.

**Other Claims:**
List any other claims that need supporting data and provide the data.

List in a table format the appropriate assay and timeframe for the evaluation that you used for each of the claims.

**Color, Scent or Flavor Additives:**
You should identify any color, scent, or flavor additive used in manufacturing medical gloves. You should provide the chemical name and composition of the color, scent, or flavor additive used and include biocompatibility data to support safe use of the additive.

**Labels, Labeling, and Advertising:**
The proposed labeling should include basic information (21 CFR 801) and appropriate caution statements. We recommend that you include identified copies of all labeling or proposed labeling, including promotional literature.

**Sterility:**
Are these examination gloves labeled as sterile?

YES _____ NO _____

If YES, state sterilization method (radiation, gas, etc.) used:
_____

Sterility Assurance Level (SAL): _____

The SAL is the statistical probability of a glove not being sterile after going through the validated sterilization cycle. The SAL should be $10^{-6}$ or better for a sterile glove.

Provide the method used to validate the sterilization cycle. Validation data is not required to be submitted in the 510(k).

_____
_____
_____
_____
_____

If Radiation sterilization, dose in Kilograys _____

If EtO Sterilization, reference the methods for determining residues and state the level of residue in parts per million (PPM):

Test Methods _____
Ethylene Oxide _____
Ethylene Chlorohydrin _____

Describe packaging used to maintain sterility:

_____
_____
_____

**Sterilizer:**

Name_____

Street Address_____

Country_____

Phone No. _____ Fax No. _____

Registration Number of Sterilizer: _____

> If sterilization is done by a contractor, the glove manufacturer should have a contract with the contract sterilizer that meets the specifications of 21 CFR 801.150(e). An importer may need two written agreements: one with the foreign manufacturer and a second agreement with the contract sterilizer.

**Expiration Date:**

If you want to include an expiration date on the labeling of the gloves covered by this 510(k) submission, specify the length of the expiration period in months and years for which you have valid supporting data. You should maintain data that supports expiration dating of the gloves.

**Biocompatibility:**

You should evaluate the biocompatibility of finished gloves and submit the result in an identified attachment. You should cite the specific test methods used and state the results obtained, i.e., "under conditions of the tests, the finished sterile gloves were not (or were) sensitizing and were not (or were) irritating."

Please refer to 510(k) Format Tips available at http://www.fda.gov/cdrh/devadvice/314311.html for additional tips on the format of a 510(k) submission.

# 7 SURGEON'S GLOVES

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## POWDER-FREE

Powder-free surgeon's gloves may be lubricated with small amounts of silicone or other suitable lubricant or be coated with a non-tacky polymer. A Premarket Notification (510(k)) submission should include a full characterization of the lubricant or coating such as the chemical identity, specifications, and biocompatibility.

## FORMAT FOR PREMARKET NOTIFICATION 510(k)

This section contains a suggested format for the submission of a Premarket Notification (510(k)) for surgeon's gloves. FDA does not require this format; however, you may use it as a guide for submitting the information to FDA. This format should increase the completeness and accuracy of your submission and reduce the time needed for review of your submission.

Although a single 510(k) submission for colored, flavored, or scented gloves may include more than one color and/or flavor or scent, you should test each glove type separately as a finished glove, for biocompatibility and all physical characteristics. Data for multiple types of gloves should be in separate attachments.

The person having direct or contractual control over sterilization should submit the 510(k) for surgeon's gloves. If the manufacturer does the sterilization or contracts for the sterilization, the manufacturer submits the 510(k). For imported prelabeled "sterile" but not-yet-sterilized surgeon's gloves, the importer that contracts for the sterilization should submit the 510(k) to FDA. However, the submitter should identify the manufacturer of the gloves in the submission.

A 510(k) submission should be complete; that is, you should not reference information from a previous 510(k) submission.

We recommend that you identify all attachments with the topic and the submitters name, street address, phone, and fax numbers. You should number the pages in your submission and attachments and include a table of contents. Do not include extraneous information such as copies of standards and details of test equipment.

**Sample Format for a Premarket Notification (510(k)) for Surgeon's Gloves**

We recommend that you follow the Abbreviated 510(k) format provided in the guidance document, "Format for Traditional and Abbreviated 510(k)s" available at http://www.fda.gov/cdrh/ode/guidance/1567.html The guidance document will help you create a complete 510(k). Pertinent elements of a 510(k) are reiterated below and are described in the guidance.

- Medical Device User Fee Cover Sheet (Form FDA 3601). See 510(k) Review Fees at http://www.fda.gov/cdrh/devadvice/314a.html for additional information.
- CDRH Premarket Review Submission Cover Sheet available at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf or http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.doc
- Cover letter as described in the format guidance
- Table of Contents (recommended)
- Indications for Use available at http://www.fda.gov/cdrh/devadvice/314312.html#link_6
- 510(k) Summary (21 CFR 807.92) or 510(k) Statement (21 CFR 807.93). See Chapter 5 of this manual.
- Truthful and Accuracy Statement (21 CFR 807.87(k)) available at http://www.fda.gov/cdrh/manual/stmnt2.html

- Provide items required under 21 CFR 807.87 (Information required in a Premarket Notification submission). We recommend the following format for a patient examination glove 510(k) submission.

**Executive Summary:**
We recommend you that you provide an executive summary of the 510(k), which should include a concise description of the device, including the indications for use and concise summary for any performance testing in the submission. We recommend that you identify all variations (for example, various colors) of gloves covered in the 510(k) submission. If this submission is for a modification of a surgeon's glove cleared by FDA for marketing, include the 510(k) number of the cleared glove.

**Classification Information:**
Device Class: Class I
Device Description of Substantially Equivalent Device:
Surgeon's gloves - 21 CFR 878.4460

**Type:** (check one)
[ ] Type 1 - gloves compounded primarily from natural rubber latex, or
[ ] Type 2 - gloves compounded primarily from rubber cement or synthetic rubber latex.

**Product Code:** ( check one )

[ ] Surgeon's Glove - 79KGO
[ ] Glove Liners - 79KGO
[ ] Autopsy Gloves – 79KGO

**Composition of Gloves:** ( check one)

[ ] Latex [ ] Latex Polymer Coated
[ ] Synthetic Polymer [ ] Co-Polymer
[ ] Other, specify polymer(s) below, including any amount of natural rubber latex:

Describe polymer or "other": _____

**Device Description and Specifications:**

Overall Length: _____ mm minimum
Width: _____ mm minimum (for medium glove)
Palm Thickness: _____ mm minimum
Finger Thickness: _____ mm minimum
Tensile Strength:
before aging _____ Mpa minimum
after aging _____Mpa minimum
Ultimate Elongation:
before aging _____% minimum
after aging _____ % minimum
Pinhole AQL: _____

If latex gloves:
Does the above data for your latex surgeon's gloves meet all the current specifications listed in the ASTM standard D3577 or an equivalent consensus standard?

YES ____ NO ____

If NO, explain why in an identified attachment and state the equivalent standard to which your gloves conform.

If synthetic polymer gloves:
Does the above data for your polymer surgeon's gloves meet all the current specifications listed under ASTM standard D3577 or an equivalent standard for gloves composed of the specific synthetic polymer?

YES ____ NO ____

If NO, state the glove composition and all of your specifications in an identified attachment; and state the equivalent standard to which your gloves conform.

**Specialty Surgeon's Gloves:**
If the submission contains a special claim, include data in an identified attachment to show that the specialty surgeon's gloves are safe and effective for the special claim.

**Former Release Powder or Chemical:**
(If none is used, state that no release powder or chemical is used.)

Release Powder
or Chemical: _____

Supplier : _____

Specifications: _____

**Absorbable Dusting or Donning Powder:**
(If none, state "powder-free.")

Note: ASTM standards do not allow Talc on the surface of medical gloves.

NDA, ANDA or PMA number: _____

Supplier:_____

Address:_____

Brand Name:_____

Specifications: _____

**For Finished Powdered Gloves:**
Weight of all types of powder on a glove _____ +/- _____ milligrams per $dm^2$. Powder should be measured by ASTM D6124 or an equivalent test method.

**Weight of Residual or Trace Powder Residue on "Powder-free" Gloves:**
Weight of all types of residual or trace powder on finished powder-free glove _____ +/- _____ mg per glove determined by ASTM D6124. The weight of trace powder should not exceed 2 mg per glove or the limit in the ASTM standard.

If the gloves are powder-free and the process includes any mold / former release or donning powder, then the applicant should provide items 13.1 through 13.5 below. If the gloves are "powder-free" and the manufacturing process does NOT include any powder, then the applicant should complete items 13.4 and 13.5 below.

Describe the powder(s) introduced at any stage of the glove manufacturing process.

In an identified attachment, describe in detail the process to remove the added powder(s).

In an identified attachment, include and describe the finished glove release specification supporting the "powder-free" claim and a brief summary of final product testing to ensure finished gloves meet this specification. (You should use the ASTM D6124 method or an equivalent method for measuring residual or trace powder.)

Describe in an identified attachment how the glove is designed or manufactured to compensate for the lack of donning powder, or reasons why compensation is not necessary, including a full chemical characterization (e.g., chemical identity, specifications, biocompatibility) of any material used to facilitate glove donning, such as silicone or polymer coating on the glove. If a donning lubricant is used, state the composition and include biocompatibility data for the lubricant in an identified attachment; also state the name, manufacturer, and address below:

Lubricant
Generic Name: _____

Lubricant
Brand Name(s): _____
Chemical Name: _____

Lubricant
Manufacturer: _____

Address: _____

_____

We recommend that you should certify that your finished sterile "powder-free" gloves meet ASTM D3577 standard or an equivalent standard for latex and polymers.

**Protein Level of Natural Rubber Latex Gloves:**
State the protein level as measured by a standard method recognized by Center for Devices and Radiological Health (CDRH) _____ mcg/$dm^2$.

Was a Standard Test Method used to determine the protein level?

YES _____ NO_____

Specify the Standard Test Method used,
including the year _____

If no, include a complete description of the test method used and data showing how it correlates with a recognized standard method. You may check the CDRH website for a list of currently recognized standard test methods. The searchable standards database is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

The protein testing was performed on the finished gloves that have undergone real time aging or accelerated aging per ASTM D3577:

YES _____ NO _____

We recommend that you include a summary of test results from samples of at least one lot of gloves that supports your stated protein level.

**Protein Control:**
Specify what test will be used for determining protein content during routine production: _____.

If this is not a Standard Test method, include data correlating the routine quality control method to a recognized standard test method.

**Chemical Sensitivity Claim:**
If your labeling makes claims regarding the reduced potential of chemical sensitization or reduced reaction-inducing potential of your gloves in allergic individuals, you should provide supporting data in an identified attachment. We recommend the attachment present a summary of the data from appropriate testing.

**Other Claims:**
List any other claims that need supporting data and provide the data.

List in a table format the appropriate assay and timeframe for the evaluation that you used for each of the claims.

**Color, Scent, or Flavor Additives:**
You should identify any color, scent, or flavor additive used in manufacturing medical gloves. You should provide the chemical name and composition of the color, scent, or flavor additive used and include biocompatibility data to support safe use of the additive.

**Labels, Labeling, and Advertising:**
The labeling should include basic information (21 CFR part 801) and appropriate caution statements. We recommend that you include identified copies of all labeling or proposed labeling, including promotional literature. If the gloves are powdered, labeling should include the statement, "Powdered with Absorbable Dusting Powder."

**Sterility:**
State sterilization method (radiation, gas, etc.) used:_____

Sterility Assurance Level (SAL): _____

The SAL is the statistical probability of a glove not being sterile after going through the validated sterilization cycle. The SAL should be 10-6 or better for a sterile glove.

Provide the method used to validate the sterilization cycle. Validation data is not required to be submitted in the 510(k).

_____
_____
_____
_____
_____

If radiation sterilization, dose in Kilograys: _____

If EtO sterilization, reference the methods for determining residues and state the level of residue in parts per million (PPM):

Test Methods _____
Ethylene Oxide _____
Ethylene Chlorohydrin _____

Describe packaging used to maintain sterility:

_____
_____
_____

**Sterilizer:**

Name_____
Street Address_____
Country_____

Phone No. _____ Fax No. _____

Registration Number of Sterilizer: _____

If sterilization is done by a contractor, the glove manufacturer should have a contract with the contract sterilizer that meets the specifications of 21 CFR 801.150(e). An importer may need two written agreements: one with the foreign manufacturer and a second agreement with the contract sterilizer.

**Expiration Date:**

If you want to include an expiration date on the labeling of the gloves covered by this 510(k) submission, specify the length of the expiration period in months and years for which you have valid supporting data. Data should be maintained by the manufacturers to support expiration dating of their gloves. (See Chapter 4 for labeling guidance.)

**Biocompatibility:**

You should evaluate the biocompatibility tests on finished gloves and submit the result in an identified attachment. You should cite the specific test methods used and state the results

obtained, i.e., “under conditions of the tests, the finished sterile gloves were not (or were) sensitizing and were not (or were) irritating.”

Please refer to 510(k) Format Tips available at http://www.fda.gov/cdrh/devadvice/314311.html for additional tips on the format of a 510(k) submission.

# 8 QUALITY SYSTEM

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## INTRODUCTION

### Quality System Regulation

Manufacturers of medical gloves must meet the requirements of the Quality System regulation for medical devices (21 CFR part 820). The Quality System regulation at 21 CFR 820.5 states that "each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device...manufactured." This system must meet the requirements of the Quality System regulation.

Proper quality control procedures help to control or eliminate manufacturing defects, such as pinhole defects. FDA also believes that compliance with the Quality System regulation and implementation of design controls will minimize water soluble proteins, chemical residues, and other problems common to the manufacture of medical gloves.

This chapter provides guidance that is particularly relevant to the manufacture of medical gloves and other natural rubber latex medical devices. This chapter does not cover all requirements of the Quality System regulation.

## DESIGN CONTROLS

The design control requirements are basic controls needed to ensure that the device being designed will perform as intended when produced for commercial distribution. Although surgeon's gloves are subject to design control requirements (21 CFR 820.30(a)(2)(ii)), patient examination gloves are not.

### Design Input for Medical Gloves

When developing design inputs for a new or modified glove design, you should answer questions pertaining to the intended use of the device as well as the needs of users and patients. The questions and answers will vary for different types of gloves and accessories. Some typical design input questions include:

Where will the new glove be used?
Who will use the new glove?
How will the new glove be used?
With what devices will the new glove be used?
Does the glove need to be resistant to certain chemicals?
How long will the new glove be used?
What is the appropriate labeling and packaging?
What are the regulatory requirements for the glove and any performance claims?
Are there any other questions that are specific to the glove you are developing?

Design input requirements should identify all of the desired performance, physical, safety, and compatibility characteristics of the proposed glove design. Design input also includes requirements for labeling, packaging, and manufacturing. You should consider shelf life under design input as part of the activities to meet user and patient needs. FDA considers shelf life to be a significant factor in meeting user needs. The design input requirements are ultimately converted to the specifications for the finished glove.

You must have a design input requirement procedure (21 CFR 820.30(c)) in order to develop the glove specifications. The specifications, among other factors, should address:

1. Performance and efficacy;
2. Human factors, fatigue, donning, color, and odor;
3. Length, cuff, size, and thickness;
4. Chemical safety;
5. Allergenicity (protein levels);
6. Pinhole AQL;
7. Biocompatibility;
8. Glove compatibility with blood, saline and any intended chemical contact;
9. Environmental compatibility;
10. Packaging (in a separate specification document);
11. Labeling (which may provided in a separate document or in the glove primary specification, as appropriate);

12. Special labeling claims;
13. Any other regulatory requirements; and
14. Professional associations' recommendations.

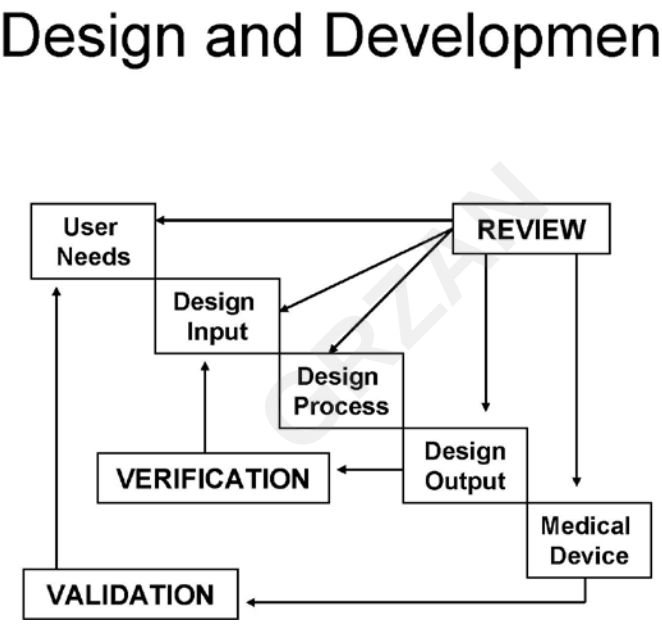
The final glove specifications should cover all significant glove characteristics. The glove specifications may refer to other specifications or standards. Specifications should address characteristics or factors such as biocompatibility (chemicals and proteins), barrier integrity, packaging protection, shipping stability, and shelf life, if applicable.

**Design Verification**

You must establish and maintain procedures for verifying the device design (21 CFR 820.30(f)). Design verification confirms that the device design meets the design input requirements. You should verify the design of gloves, packaging, and any subsequent changes by testing parameters such as tensile strength, elongation, barrier integrity (pinholes), protein residues, chemical residues, biocompatibility, correct labeling, and shelf life. We recommend that you use test methods provided in recognized consensus standards for your verification testing whenever possible.

**Design Validation**

While design verification confirms that the device design (outputs) meets the design requirements (inputs), design validation is conducted to determine whether the device meets user needs. The difference between design verification and design validation is illustrated in the following diagram:




Validation for medical gloves may include use under real or simulated conditions. Validation assures that the donning ability, strength, thickness, feel, size, shape, texture, holding ability, tactile sensitivity, lack of fatigue, lack of irritation, color, and odor of the gloves are satisfactory to users.

Generally, clinical testing is not required for gloves that are substantially equivalent to gloves legally marketed in the U.S. However, if clinical testing is conducted, e.g., testing for skin sensitization to chemicals, you should perform appropriate laboratory and animal verification (e.g., performance, reliability, and biocompatibility) testing prior to human clinical or simulated use testing.

## DEVICE MASTER RECORD

Title 21 CFR 820.3(j) states a "Device master record means a compilation of records containing the procedures and specifications for a finished device." A Device Master Record (DMR) is a comprehensive record of all of the procedures and instructions required to manufacture each type of glove. A DMR contains or refers to the location of documents for manufacturing and processing activities, such as procurement, processing, labeling, test and inspection, and packaging. The DMR also contains information on the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, acceptance criteria, packaging, and labeling of a finished glove.

A DMR for medical gloves manufactured by complex processes, such as latex dipping, usually consists of many documents. For convenience, many medical glove manufacturers generate an index or table of contents which lists all of the documents in a DMR. The DMR should contain a glove (device) specification. Generally, a medical glove specification will include the following:

- product trade and common name(s)
- intended use(s)
- performance characteristics, such as tensile strength and elongation
- regulatory classification
- physical characteristics, such as cuffs, thickness, length, and size
- environmental limitations and product shelf life or expiration date
- user safety characteristics such as a pinhole and chemical residue limits
- water-extractable protein limit
- powder/particulate/debris limit
- packaging and labeling specifications

Exhibit #1 provides a sample specification for inclusion in the Device Master Record.

A DMR should contain specifications for the content and design of labeling. Labeling claims should match glove characteristics and contain required labeling. Gloves that have false or misleading labeling are misbranded under section 502 of the Act. (See chapter 4 on labeling.)

### Record Retention

The Quality System regulation at 21 CFR 820.180(b) states "All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer." You should retain records for most medical gloves for two years or for as long as the labeled expiration/shelf-life date, whichever is longer.

**DOCUMENT CONTROL**

Many written documents are needed to manufacture gloves. Written procedures should cover the following areas:

- glove design
- processes
- components, coagulants, dewebbers, donning lubricants
- labeling and packaging
- colorants, flavors, odorants, antimicrobials, anti-ozonants, anti-oxidants
- environmental control, facilities, employee practices
- production and measuring equipment
- manufacturing materials

Specifically, we recommend that written procedures address the following:

- cleaning tanks and equipment in accordance with a schedule
- preventing or reducing of air bubbles during compounding
- ball milling chemicals to yield proper size and prevent contamination
- filtering compounded polymer solutions
- inspecting formers on and off line for defects and debris
- washing formers each (or as designated) line cycle
- protecting wet formers from dust and other debris
- controlling the environment by screening or closing doors and windows
- protecting dipping tanks from dust and other debris
- maintaining covers, shields, and ledges to reduce debris falling into processing tanks
- controlling the use of grease and oil to eliminate drips into the processing tanks,
- inspecting lines, tumblers, etc., to assure there are no protrusions, vibrations that could cause product defects
- cleaning equipment
- cleaning floors
- maintaining floor or other waste material drains
- controlling leach tanks function
- controlling protein wash/rinse tanks function (i.e., manufacturing material is being removed)
- controlling chlorination and neutralization
- identifying and controlling finished gloves to prevent mix-ups

- analyzing defective gloves (when acceptance criteria are not met) to determine the cause of the problems,
- personal hygiene, such as hand washing

You should establish and maintain procedures to control all documents (21 CFR 820.40). Whenever there are changes to standard operating procedures, quality assurance procedures, data forms, and product specific documentation, the review and approval must come from individual(s) in the same function or organization that reviewed and approved the original (21 CFR 820.40(b)). See the Quality System manual for additional information on change control.

## INCOMING AND IN-PROCESS ACCEPTANCE ACTIVITIES

### Components and Manufacturing Materials

Components are materials used during manufacturing that are intended to be part of the finished gloves. Examples of such products are latex concentrate, various chemicals that are mixed with the latex or polymer during compounding (such as antioxidants), and donning lubricant.

Manufacturing materials are substances used to help in the manufacturing process but are not intended to become part of the finished gloves. Examples include ingredients contained in the dipping compound (such as accelerators), former release chemicals, and any detergents that are used to clean the formers. Corn starch (powder) is also a manufacturing material if it is added and then removed for "powder-free" gloves.

### Component Qualification

Qualification is the determination of suitability of components and consists of verifying through documented testing, evaluation, and review that a manufacturing ingredient or component will reliably perform its function. Well characterized manufacturing ingredients or components that are used in their normal application may need minor testing. New products, such as donning lubricants, protein modified latex, or new accelerators, will require substantial testing.

For surgical gloves, you should maintain a design history file of any qualification (verification) testing of components, raw materials, and manufacturing materials. This record should include the product identity, testing methods that were used, who performed the testing, date, and the actual test data and results.

### Specifications for Incoming Components

Specifications for components and manufacturing materials should state essential properties to assure the quality of the finished product. The specifications should adequately describe the characteristics, dimensions, design, chemical purity, performance, and any other feature

or parameter necessary to assure receipt of the product desired. For some components, such as donning powder, the specifications should include a limit on microorganism contamination. Component and material specifications should be part of the device master record.

Natural rubber latex is a biologically produced substance that may vary considerably depending on climate, season, local environmental factors (including soil composition), and specific tree varieties. Therefore, you should have as many applicable specifications for the incoming latex as feasible in order to reduce some of the inherent variability in this component. You should be aware that various applicable standard tests and specifications are included in documents, such as ASTM D1076-02, Standard Specification for Rubber-Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex.

**Acceptance Criteria, Testing, and Documentation**

To the extent feasible, you should have specific acceptance criteria for components and manufacturing materials. Acceptance criteria are the attributes of a product that determine its acceptability, such as appearance, color, dimensions, mechanical stability, percent solids, preservative levels, protein levels, viscosity, purity, pH, or performance characteristics.

You should document the inspection, testing, and acceptance or rejection of raw materials, manufacturing ingredients, and components. Exhibit #2 provides a sample record for receiving incoming latex.

If you use a contract laboratory to test components, materials, and manufacturing materials, the laboratory becomes an extension of the glove manufacturer's quality system. The glove manufacturer is responsible for assuring that the contractor's test and inspection procedures and quality system are acceptable. Typically, you can obtain this assurance by documented audits.

**Component Storage**

You should store components so that they are protected from moisture, dirt, and insects. You should store components or materials, such as latex and starch, in a manner that retards the growth of microorganisms. FDA suggests that you store components and manufacturing materials under conditions that prevent their deterioration. You may store ceramic formers and other items not affected by the environment in sheds or outside.

**In-Process Testing**

You should perform in-process testing on the dipping compound as well as the glove to determine if the manufacturing process is on target to meet your specifications. In-process testing may include testing of the uncured compound, the cure status of the dipping compound (whether the compound is ready to dip), and thickness, tensile strength, length, and water leak testing of the glove. Also, you should test for powder, if it is a powder-free

glove. You can find a sample of an in-process record, Analysis of Latex Compounding, in Exhibit #3.

## PROCESS VALIDATION

Process validation is a means by which the manufacturer establishes that its manufacturing process is capable of consistently producing a product that conforms to the specifications as outlined in the device master record. Process validation is a key element in developing process controls. A properly validated and controlled process will reduce scrap and rework resulting in increased efficiency. Examples of processes that should be validated include compounding, dipping, leaching, chlorination, sterile packaging, and sterilization.

If there is an increase in nonconforming product or process deviations occur, you should review and evaluate the process, and you should perform revalidations where appropriate. Changes to the manufacturing process, such as new equipment or a new compound, may require revalidation prior to implementation of the change.

## PROCESS CONTROLS

Each manufacturer must establish production and process controls, as appropriate, to ensure that a device conforms to its specifications (21 CFR 820.70(a)). These controls should reflect the ranges of parameters established during the previously conducted process validation.

You should consider process controls for the following processes: compounding, maturation, dipping, curing, bleaching, drying, powdering or removal of powder, and rinsing. Also, you should control vibration which causes air bubbles in the dipping tanks. Exhibit #4 shows a table providing the impact of processes that affect the finished glove characteristics. The table provides examples of parameters for each process that you should consider for process controls. Exhibit #5 provides a typical example of a monitoring and process parameter control record.

Inadequate process control can lead to nonconforming product. For example, patient exam gloves were insufficiently dried and subsequently packaged and distributed in a moist condition. The lot was later tested and found to have Aspergillus and Fusarium molds and recalled from the market. One way this situation may have been prevented is if the firm had monitored in-process controls during the manufacturing process. Monitoring the humidity and/or moisture content during the drying cycle could have revealed the problem. At this stage, the firm may have been able to rework (re-dry) the gloves which could have avoided the product recall.

### Manufacturing Materials

Under the definition in 21 CFR 820.3(p) of the Quality System regulation, manufacturing materials include "concomitant" or by-product constituents. Concomitant constituents are substances that are unavoidably present in the components and manufacturing materials but are not intended to be present in the finished device. These include water-soluble natural rubber proteins present in the latex concentrate. These proteins do not contribute to the glove barrier, because they are not bound into the latex film but readily leach out. By-products are substances formed during mixing by reactions between various components and manufacturing materials. These also include various calcium salts.

Manufacturing materials such as mold release compounds, cleaning agents, lubricating oils, by-products, and other substances used to facilitate manufacturing are procured and received the same as components. You should establish, maintain, and document procedures for the removal of manufacturing materials when they could reasonably be expected to have an adverse effect on product quality. You should remove manufacturing materials or limit them to an amount that does not adversely affect the quality of the glove. Because natural rubber latex proteins can adversely affect the safety of medical gloves, you should establish and validate procedures to reduce the water soluble proteins to ensure that it is removed or limited to an amount that does not adversely affect the gloves's safety.

**Control, Use, and Removal of Manufacturing Materials**

You should carefully consider manufacturing materials that may adversely affect the finished glove. You should design each process to use a minimum amount of adverse chemicals to reduce costs and removal efforts and increase the safety of the glove.

For medical gloves, processing of raw latex, and leaching and washing processes are commonly used to reduce or remove natural water-soluble proteins and remove adverse materials, such as processing chemical residues. When residues from sterilization agents such as ethylene oxide need to be removed, instructions for aeration are necessary.

When you add starch to medical gloves to expedite handling and then remove it during further processing (for example, during the production of some "powder-free" gloves), the starch becomes a manufacturing material. You should use a written processing and test/inspection procedure to assure that powder residues on the finished gloves meet finished device specifications.

**Water-Soluble Proteins.** Water-soluble proteins on latex gloves may be a potential cause of allergic reactions. Processing controls should include the reduction of water-soluble proteins. You should remove them by:

- reducing or removing the proteins in the raw latex,
- using and controlling pre-cure leaching and post-cure washing processes,
- assuring that the leaching tanks and spray or washing tanks use water that is flow-controlled and continually refreshed to avoid protein saturation, and
- leaching and washing for an appropriate time.

You should perform washing before and after curing, because proteins become more water-soluble and/or move to the surface of latex gloves during heat curing. This allows you to remove the protein more efficiently. You should complete the washing before you apply the final donning powder or lubricant, if applied.

Each manufacturer should establish the temperature of the leaching and washing water because the temperature needed varies based on the parameters of the overall compounding, dipping, and curing methods. Studies indicate that the purity (flow rate) and agitation of the leach water and total leaching time are more important than water temperature.

Surface treatment of the cured latex glove with chlorine or similar agents denatures surface constituents such as water-soluble proteins. These treatment processes also wash and rinse away proteins and manufacturing residues. Chlorine is an adverse manufacturing material which can cause deterioration of the gloves. You should remove it from the gloves after chlorination by washing, neutralization, or other appropriate methods. The chlorination process includes process control and validation.

You should test water-soluble proteins during routine production. You may test protein levels using the FDA-recognized standard, ASTM D5712, Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method, or an equivalent consensus standard.

Trained personnel should develop, validate, document, implement, and control the processes used to control water-soluble proteins and manufacturing materials (see 21 CFR 820.25).

**Manufacturing Chemicals.** You should remove manufacturing chemicals, such as vulcanization accelerators and detergents, to the extent that they do not adversely affect the finished glove. Reports of type IV sensitivity reactions have been associated with gloves that contain residual amounts of these manufacturing chemicals.

You can remove manufacturing chemicals by some of the same methods used to remove protein. You should develop leaching, washing, surface treatment, or other processes for removing adverse manufacturing materials. You should also validate, document, and continuously control the processes in order to meet the established specifications.

**Maintenance and Inspection of Equipment**

According to 21 CFR 820.70(g)(1), you must establish and maintain a schedule for the adjustment and cleaning of equipment. For example, you should periodically strip and clean the maturation tank of any residue to avoid contamination. The formers should have a routine cleaning schedule because build up of residues can cause thin spots and holes in the gloves. In addition to the in-line cleaning, you may need periodic maintenance of formers to remove the build up of residues. You should lift, or remove and repair, or replace defective formers. Because lubricant for production equipment can fall into dipping tanks, you should inspect the equipment for excess lubricant and periodically clean the equipment.

To properly maintain equipment, manufacturers should:

- establish a written schedule for performing these activities,
- post the schedule or make it readily available to employees,
- document the activities, the individuals conducting the activities, and the date,
- audit the activities and document the audit, and
- keep maintenance records for each piece of equipment.

When adjustment is necessary to maintain proper operation due to deterioration of parts or other reasons, post the inherent limitations and allowable tolerances of the equipment or make these readily available to personnel responsible for making adjustments.

**Contamination Control**

For each area in the building where you process components and gloves, you should control any element that you determined might cause contamination. The contaminants include dust, paint chips, rust, starch residues, protein residues, microorganisms, humidity, temperature, and static electricity. If sources of contaminants are located above the manufacturing equipment, you should consider covering or enclosing portions of the dip line or any other area that could be affected by debris. You should clean equipment as needed by methods that will reduce or prevent contamination of tanks, formers, and gloves with dust and other debris.

Buildings should be appropriately constructed to prevent, reduce, and control contamination, and support the manufacturer's environmental control program. For example, controlling dust may require that you pave driveways and parking lots. Floor sweeping and floor polishing scatter dust can contaminate wet formers, coagulant dipping tanks, latex/polymer dipping tanks, and finished gloves. You should clean floors and equipment by methods that minimize the amount of debris released into the environment.

You should perform all manufacturing and labeling operations for low protein or synthetic gloves in a separate area to avoid protein contamination by latex gloves. Synthetic polymer gloves, polymer-coated latex gloves, or any gloves with a labeled or controlled protein level should not be dipped in any tank (particularly starch slurry tanks) or tumbled in dryers where regular protein coated latex gloves have been produced, unless you clean the tanks thoroughly before the production of the low- or protein-free gloves. FDA recommends that manufacturers dedicate lines specific to the manufacture of synthetic gloves to avoid protein contamination.

**Environmental Control**

Where environmental conditions could reasonably be expected to have an adverse effect on product quality, you must establish procedures to control the environmental conditions (21 CFR 820.70(c)). You should establish and maintain an appropriate system for regular monitoring and documenting the control of environmental factors that apply to your specific situation.

You should consider environmental factors, such as lighting, ventilation, temperature, humidity, static electricity, insect and pest control, and particulates. If you use rodenticides, insecticides, or similar agents, you should establish written procedures for limiting their use and removing them from work surfaces. These procedures are to prevent any adverse effect on the manufacturing process or the device. You should cover finished gloves, solution tanks, and other appropriate items during the application of pesticides to the room.

You should store packaging and starch in a clean, dry, insect-free area. You should preserve latex to prevent bacterial growth. You should store components such as starch that support bacterial growth in a controlled environment such as sealed containers or bags. You should not use unfiltered air to dry washed formers or coagulant-coated formers, because the resulting contamination may cause pinholes. You should not use unfiltered factory air to cool or dry finished surgeon's gloves. You should have screens in open windows, and doors should be screened to control insects.

**Bioburden Control**

Bioburden is an environmental factor that needs to be controlled for sterile surgeon's gloves, but it is also important in the manufacture of nonsterile gloves. The failure to control bioburden may result in mold on the finished product.

Medical gloves, particularly those powdered with starch, can support the growth of micro-organisms. Appropriate processing controls should include:

- purchasing starch with a low bioburden,
- properly storing the starch until it is used,
- applying starch per established procedures,
- cooling the starch slurry and/or using an antimicrobial in the starch slurry tanks,
- sampling finished gloves to assure that excessive starch is not applied,
- keeping the finished gloves clean,
- establishing and meeting a dryness specification for finished gloves, and
- protecting finished gloves from the environment.

Filthy or contaminated water may also be a major source of microbes on finished gloves. You should monitor and appropriately treat water used in processing the glove, especially near the end of the manufacturing process, such as post-cure washing, to control the bioburden on the glove.

You should refer to ANSI/AMMI/ISO 11737-1:1995, Sterilization of Medical Devices—

Microbiological methods—Part 1: Estimation of Population of Microorganisms on Product for guidance on bioburden testing.

**Personnel Practices**

You should establish and maintain procedures for personnel to follow to reduce contamination and any other adverse effects on the gloves. Procedures should include hand washing requirements. Personnel should not wear jewelry or have sharp fingernails. Additionally, eating and smoking may adversely affect the finished glove. You should confine these activities to designated areas.

## FINISHED GLOVE ACCEPTANCE ACTIVITIES

Finished glove acceptance procedures should demonstrate that the gloves meet the manufacturer's acceptance criteria. The finished device evaluation should include inspection and testing of samples of packaged gloves. A manufacturer's evaluation of finished glove lots usually includes appropriate in-process inspection and testing performed on representative samples. You should record the evaluation data for finished glove lots in the device history record (DHR). You should review and accept the DHR before releasing the lot for distribution.

Glove evaluation may include the following parameters:

- barrier integrity, including pinholes and embedded debris,
- length, width, thickness,
- weight,
- elongation and tensile strength,
- cuffs/beads,
- powder and/or lubricant level,
- measurement or indication of manufacturing material residues,
- measurement or indication of proteins or allergens,
- moisture content or dryness level,
- fisheyes, webbing, or folds,
- package integrity,
- bioburden count,
- labeling,
- visual tests, such as color and material uniformity.

Your quality system procedures should describe the finished device test methods and acceptance criteria, including sampling procedures and AQL. You should reference any standard test methods that are used. Information on test methods for water leak testing, protein, tensile strength, and powder residue is available in consensus standards. See Chapter 10, Voluntary Standards, for more information on consensus standards. For water leak testing, FDA uses the methodology in 21 CFR 800.20 for its regulatory testing of all medical gloves (of all materials).

## NONCONFORMING PRODUCT

If a lot of gloves or product does not meet specifications, you should properly identify the containers of rejected gloves and place them in a separate quarantine area or in a specially identified area to prevent mix-ups. If nonconforming product is investigated, you should add the results to the corrective and preventive actions (CAPA) system. According to 21 CFR 820.90(b)(1), you must document the disposition of nonconforming product. The records should state whether you returned or scrapped the gloves, components, materials, or other products.

### Reworked Gloves

You must establish and maintain procedures for rework to include retesting and reevaluation of reworked nonconforming product (21 CFR 820.90(b)(2)). Reworked product should meet the original specifications. You should evaluate reprocessing to assure that gloves will not be adversely affected and you should document the results of the evaluation.

Procedures for reworking should specify the types of nonconformances that may be reworked. These procedures should document the specific tests and processes to be performed. You should base these procedures on studies that measure the effects of reprocessing operations.

Reworked product is nonconforming product until it meets all finished device acceptance criteria. You should identify reworked product to distinguish it from acceptable product and components.

## LABELING AND PACKAGING

The Quality System regulation has specific requirements for labeling and packaging design, as well as for labeling and packaging operations (21 CFR 820.120, 820.130)). Labeling includes dispenser box labels, case labels, package labels, and directions for use, such as caution statements.

### Area Separation and Inspection

You should separate all labeling and packaging operations performed at the same time, as necessary, to assure there are no mix-ups between similar labels or various sizes or types of gloves. Before beginning any packaging and labeling operation where a mix-up could occur, you should examine the production area and equipment to make certain that you have removed any glove and labeling materials from previous operations. You should destroy unused labeling that contains a pre-coded manufacturing date, expiration date, or lot number; you should not return it to the label storage area.

A designated individual should examine the labeling for accuracy, in accordance with the device master record, prior to initiating the labeling operation. The examination should include the expiration date.

**Packaging**

An effective primary package for a medical glove should be designed and developed along with the product by considering glove characteristics, contamination control, sterilization process, sealing, labeling, secondary packaging, shipping, environment, shelf life (expiration date), end use, and FDA regulations. The primary package and the shipping container should protect gloves adequately under all reasonable conditions from original packaging to final use. For sterile gloves, you should validate the packaging operation. You should either compile complete storage and stability data for packaging for sterile gloves or obtain the data from the packaging supplier.

**Shipping for Further Processing**

It is common industry practice for non-sterile gloves labeled as "sterile" to be shipped to a contract sterilizer. You should conspicuously mark each pallet, carton, or other designated unit to show its non-sterile nature when it is introduced into and is moving in interstate commerce. See Sterilization for additional information.

**COMPLAINT HANDLING**

Each manufacturer must process complaints from all sources according to its complaint handling procedure (21 CFR 820.198(a)). You should assure that personnel in marketing, sales, engineering, and manufacturing report complaints. You should make these employees aware of this Quality System requirement through formal training and note the training in their training records.

Because FDA believes that customer complaints are underreported, user reporting for tears and leaks are considered low. Therefore, even small increases in the rate of complaints may be significant.

Customer complaints may include the following issues:

[ ] Pinholes, Tears, Thin Spots, Degradation _____

[ ] Expiration Date / Shelf Life _____

[ ] Powder, Lubricant, Tacky _____

[ ] Particulates: Type _____ Location _____

[ ] Packaging _____

[ ] Sterility _____

[ ] Labeling _____

[ ] Thickness, Mold, Appearance, Attributes _____

[ ] Dermatitis _____

[ ] Allergic Reaction _____

[ ] Describe Other Defects _____

**Complaint Analysis**

Each complaint needs to be reviewed by a designated unit and a decision made as to whether an investigation is needed. The analysis of the complaint typically includes the following information:

Sequential Complaint Number _____

Glove Type _____ Cat. Number _____

Date of Complaint Report _____ Lot Number _____

Name of Complainant _____

Nature of Complaint _____

ASSIGNEE EVALUATION & CONCLUSIONS: _____

_____

_____

_____

_____

_____

[ ] Pinholes, Tears, Thin Spots, Degradation _____

[ ] Powder, Lubricant, Tacky _____

[ ] Particulates _____

[ ] Labeling/Packaging _____

[ ] Non-Sterile _____

Thickness, Appearance, Color Attributes of:

[ ] Fingers_____ [ ] Palm_____

[ ] Crotch _____ [ ] Cuff/bead _____

[ ] Elongation _____ [ ] Tensile _____

[ ] Chemical Residues Above Spec. _____

[ ] Protein Level Above Spec. _____

[ ] Improper Use _____

[ ] Shipping Damage _____

[ ] Describe Other Defects/Problems _____

_____

_____

_____

ACTION: [ ] Recalled [ ] Replaced [ ] Credited [ ] Sales Follow-Up

[ ] Letter _____

Investigation needed []Yes []No

[ ] Referred To _____ for Further Investigation or Correction

[ ] NONE. Reason for no action _____

NOTES: _____

FINAL DISPOSITION _____

Reviewed by: Quality Assurance _____ Date _____

If requested: Engineering _____ Date _____

Production _____ Date _____

**Complaint Investigation**

Each manufacturer must evaluate complaints to determine whether an investigation is necessary (21 CFR 820.198(b)). After an analysis of the complaint, if an investigation is needed, the failure investigation and analysis should determine the actual problem or actual failure mechanism to the level necessary to correct the problem. A failure investigation may include a review of the device history records and analysis of returned product. When you diagnose the same failure, contaminant, or other problem several times, you do not need to analyze all additional gloves that are returned with the same complaint.

**Complaints Received by Distributors**

When the manufacturer is located outside the U.S., the foreign manufacturer should provide the U.S. distributor with instructions to forward any complaints to the foreign manufacturer for review and analysis. You should consider the forwarding of complaints when developing contracts or other business arrangements with importers.

**Medical Device Reporting**

According to 21 CFR 820.198(a)(3), you must evaluate complaints to determine whether the complaint represents an event which must be reported to FDA under 21 CFR 803, Medical Device Reporting. Incidents in which a device may have caused or contributed to a death or serious injury must be reported to FDA under the Medical Device Reporting program. In addition, you must report certain malfunctions. (21 CFR 803.1.) An allergic reaction may be considered a reportable event.

The MDR regulation is a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goal of the regulation is to detect and correct problems in a timely manner. You can find additional information on the Medical Device Reporting process at: http://www.fda.gov/cdrh/devadvice/351.html

**STERILIZATION**

Sterilization of medical gloves should meet a sterility assurance level (SAL) of $10^{-6}$. This means that you should design the sterilization process so that the probability of a glove being non-sterile is 1 in 1,000,000, even if the gloves originally contained highly resistant microorganisms.

You should sterilize medical gloves with a validated sterilization process. Note that some glove materials are adversely affected by certain sterilization methods. Validation of the sterilization method should demonstrate that the sterilization process does not adversely affect glove safety and effectiveness.

Refer to the Quality System manual and applicable standards, such as AAMI or ISO, for validation of sterilization processes. AAMI and ISO standards for sterilization include the following:

- ANSI/AAMI/ISO 11135- Medical devices - Validation and routine control of ethylene oxide sterilization
- AAMI/CDV 11137 Sterilization of health care products – Radiation
- AAMI/ISO Technical Information Report (TIR) 13409 Sterilization of health care products - Radiation sterilization

Additional AAMI standards are available at
http://www.aami.org/applications/search/index.cfm?currentcategory=Sterilization

**Contract Sterilization**

It is common industry practice to ship non-sterile gloves labeled as sterile to a contract sterilizer. This practice is recognized in 21 CFR 801.150(e) which states, in part, "the Food and Drug Administration will initiate no regulatory action against the device as misbranded or adulterated when the non-sterile device is labeled sterile, provided all the following conditions are met:

(1) There is in effect a written agreement which:

(i) contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization,
(ii) provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized,
(iii) acknowledges that the device is non-sterile and is being shipped for further processing, and
(iv) states in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Act.

(2) Each pallet, carton, or other designated unit is conspicuously marked to show its non-sterile nature when it is introduced into and is moving in interstate commerce, and while it is being held prior to sterilization. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine, e.g., "sterilized—awaiting test results" or an equivalent designation."

Compliance with 21 CFR 801.150(e) may require two written agreements when importing pre-labeled "sterile" but not-yet-sterilized surgeon's gloves. The two agreements are:

- one between the importer and the glove manufacturer, and
- one between the importer and the contract sterilizer.

Gloves that have been sterilized and shipped to the importer's warehouse prior to final release of the product should be properly marked as not yet released. For example, pallets or other designated units may be marked "sterilized, awaiting test results," or similar wording. The importer should have control of the gloves until final release. Prior to shipping, you should use either a highly controlled quarantine area or a label control system to prevent distribution of gloves marked "sterile," but not yet released for distribution.

## QUALITY SYSTEM AUDITS

Under 21 CFR 820.22, you must conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Individuals who do not have direct responsibility for the area being audited must conduct the quality audits. You must take corrective action(s), including a reaudit of deficient matters, when necessary. You must document the results of each quality audit, (and reaudit(s), if necessary) in a report, and management responsible for the area audited must review the report (21 CFR 820.22).

You should establish written procedures for quality audits. You should document the dates and results of quality audits and reaudits.

## EMPLOYEE TRAINING

Under 21 CFR 820.25, you must have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by the Quality System regulation are correctly performed. As part of their training, personnel must be made aware of device defects that may occur from the improper performance of their specific jobs. Personnel who perform verification and validation activities must be made aware of defects and errors that may be encountered as part of their job functions.

You must establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. You must document employee training (21 CFR 820.25).

**EXHIBIT #1 SAMPLE GLOVE SPECIFICATION (DEVICE MASTER RECORD)**

***** SAMPLE DEVICE MASTER RECORD EXAMINATION GLOVE SPECIFICATION ***** including some typical parameters.
You may modify this form and use it to meet your needs. Do not use this example as is.

| C O M P A N Y L O G O | | Page 1 of 1 |
|---|---|---|
| Title: **Glove Specification** | SOP Number | |
| Prepared by: | Date Prepared | |
| Approved by: | Date | Rev C |
| ECN notes: ECN 429 Protein limit added 8-1-96; no label claim -- no new 510k required; ECN 436 Rev B powder level changed to 10mg/decimeter $^2$ | | |
| ECN 438 Rev C protein reduced to 200 µg/decimeter $^2$ by process improvement | | |

COMPANY PRODUCT NAME: ________________

| | | | |
|---|---|---|---|
| Trade Name: | Patient examination gloves, non-sterile | | |
| Intended Use: | Medical activities except surgery | | |
| U.S. FDA Status: | Class I, Classification Number 80LYY; 510(k) marketing clearance required. Should be manufactured under quality system program. | | |
| Material: | Natural rubber latex | | |
| Donning Lubricant: | U.S.P. Absorbable corn starch | | |
| Catalog Numbers: | Crystal Touch 100S | Crystal Touch 100M | Crystal Touch 100L |
| Sizes: | Small | Medium | Large |
| Conforms to following Standards: | ASTM D3578, ISO 11193 | | |
| Overall Length: | 240 mm minimum | 240 mm minimum | 240 mm minimum |
| Width: | 80 +/- 10 mm | 95 +/- 10 mm | 111 +/- 10 mm |
| Palm Thickness: | 0.10 mm minimum | | |
| Finger Thickness: | 0.10 mm minimum | | |

| | **BEFORE AGING at 70°C** | **AFTER AGING at 70°C** |
|---|---|---|
| Tensile Strength: | 18 Mpa minimum | 14 Mpa minimum |
| Ultimate Elongation: | 650% minimum | 500% minimum |

| | |
|---|---|
| Orientation: | Ambidextrous |
| Cuffs: | Yes |
| Color: | Natural |
| Residual Powders | 10mg/decimeter $^2$ max. |
| Protein Max. | 200 µg/decimeter $^2$ max. |
| Packaging: | 100 units in dispenser box by weight |
| Disp. Carton Labeling: | Per Packaging specification P-192 Rev. C |
| Ship. Case Labeling: | Per Packaging specification P-193 Rev. B |
| Product Coding: | |

****************************** End *********************************

**EXHIBIT #2 SAMPLE COMPONENT RECORD (INCOMING CONTROLS)**

***** SAMPLE RECORD ***** Page ___ of___

Do not use without modifying to meet your specific glove and operations.

| **RECEIVING LATEX TEST DATA** | | | PROCEDURE NO.* | |
|---|---|---|---|---|
| SUPPLIER: | | Date Received | | |
| SOURCE: | | Date Sampled | | |
| LATEX GRADE: | | Lot | | |
| PARAMETER | ACCEPTANCE CRITERIA | RESULTS | Tested by and date | PASS/FAIL |
| % TOTAL SOLID CONTENT | | | | |
| MST (sec) | | | | |
| % DRY RUBBER CONTENT | | | | |
| % NON-RUBBER CONTENT | | | | |
| % ALKALINITY ( $NH_3$% ) | | | | |
| VFA NUMBER | | | | |
| KOH NUMBER | | | | |
| VISCOSITY | | | | |
| pH VALUE | | | | |
| OTHER: | | | | |
| Remarks: | | | | |
| | | | | |
| | | | | |
| | | | | |
| Reviewed by (signature): | | Date | | |

## EXHIBIT #3 SAMPLE IN-PROCESS RECORDS (IN-PROCESS CONTROL)

***** SAMPLE RECORD *****

Do not use without modifying to meet your specific glove and operations.

| **ANALYSIS OF LATEX COMPOUNDING** | | | |
|---|---|---|---|
| **DATE** | | **SHIFT** | |
| Batch Number | | | |
| Compounding Tank No. | | | |
| Date & Time Compounded | | | |
| Date and Time of Test | | | |
| | **PROCEDURE* NUMBER (Spec)** | **RESULTS BEFORE MATURATION** | **PASS/FAIL** |
| 1. pH | | | |
| 2. TSC | | | |
| 3. Precure test | | | |
| 4. $NH_3$ | | | |
| 5. VISCOSITY | | | |
| 6. OTHER | | | |
| | **PROCEDURE* NUMBER (Spec)** | **RESULTS AFTER MATURATION** | **PASS/FAIL** |
| 1. pH | | | |
| 2. TSC | | | |
| 3. Precure test | | | |
| 4. $NH_3$ | | | |
| 5. VISCOSITY | | | |
| 6. OTHER | | | |
| Remarks:<br><br>*The test & acceptance activities performed & equipment used are described in the procedures | | | |
| Tested by:<br>Signature: | | | |

## EXHIBIT #4 IMPACT OF MANUFACTURING PROCESSES (PROCESS CONTROL)

This chart indicates the possible effects of various process parameters on the performance characteristics of gloves. It can be used as a checklist for the design of gloves and associated processes. It does not cover all possible parameters. It is in keyword form; therefore, it should be used by appropriately trained persons. Do not use this checklist without modifying it to meet your specific approach to glove and process design.

**REACTIONS / PHYSICAL PROPERTIES AND SURFACE CHARACTERISTICS**

| | a | b | c | d | e | f | g | h | i | J | k | l | m | n | o | p | q | r | s | t | u | v | w | x |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COMPONENTS, PARAMETERS, AND PROCESSES** | **Irritation** | **Type IV Allergy** | **Type I Allergy** | **Barrier** | **Shelf Life** | | **Tack / Grip** | **Bricking** | **Blocking** | **Particles** | **Discoloration (5)** | **Extractables** | **Donning Ease** | **Comfort** | **Roll Down** | **Hand Fatigue** | **Thickness** | **Uniformity** | **Bioburden** | **Endotoxins** | **Spoilage** | **Modulus** | | |
| **1. RAW LATEX** - Non Rubber Solids; Ammonia; Copper & other metals; Centrifugation; Maturation | | | ✓ | ✓ | ✓ | | | | | | | ✓ | | | | | ✓ | ✓ | | | | | | |
| **2. FORMULATION** - Selection; Amount Added; Amount processed out (removed) | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | ✓ | ✓ | | | | | ✓ | | |
| **3. CHEMICALS** - Chemical purity; Microbial purity; Particle size; Supplier Change control | ✓ | ✓ | | ✓ | ✓ | | | | | | | ✓ | | | | | | | | | | | | |
| **4. PRE-PROCESSING** - Ball milling or grinding efficiency; Premixing | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | ✓ | ✓ | ✓ | | | | | | | ✓ | ✓ | | | | |
| **5. COMPOUNDING** - Correct ingredients; Correct order; Cleanliness; Homogeneity; Maturation; Stir / Fill bubbles | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | | | | | | | |
| **6. FORMERS** - Dimensions; Orientation; Length**;** Composition; Surface texture; Embossing; Cuff Width; Rotation; Dynamics; Age/wear | | | | ✓ | | | ✓ | | | ✓ | | | | ✓ | ✓ | ✓ | | | ✓ | ✓ | | | | |
| **7. COAGULANT** - Composition; Agitation; Former temperature / dry; Agitation | ✓ | ✓ | ✓ | ✓ | | ✓ | | ✓ | ✓ | ✓ | | ✓ | | | | | ✓ | ✓ | | | | | | |
| **8. LATEX DIP** - Temperature; Agitation; Level; Dwell; Foam; Drip; Fallout | | | | ✓ | | | | | | ✓ | | | | | | | ✓ | | | | | | | |
| **9. SET - BEAD (1)** | | | | ✓ | | | | | | | | | ✓ | | ✓ | ✓ | | | | | | | | |
| **10. LEACH** - Temperature; Water direction; Water speed; Dwell time; Depth; Fresh Water ratio; Water purity | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | | ✓ | | | | ✓(6) | | | | | | | | | |

| | a | b | c | d | e | f | g | h | i | J | k | l | m | n | o | p | q | r | s | t | u | v | w | x |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COMPONENTS, PARAMETERS, AND PROCESSES** | **Irritation** | **Type IV Allergy** | **Type I Allergy** | **Barrier** | **Shelf Life** | | **Tack / Grip** | **Bricking** | **Blocking** | **Particles** | **Discoloration (5)** | **Extractables** | **Donning Ease** | **Comfort** | **Roll Down** | **Hand Fatigue** | **Thickness** | **Uniformity** | **Bioburden** | **Endotoxins** | **Spoilage** | **Modulus** | | |
| **11. OVENS** - Temperature Profile; Dwell; Air circulation; Humidity **(2)** | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | ✓ | ✓ | | | | |
| **12. POST-CURE RINSE POWDERED GLOVES** Purity; Volume; Duration; Exposure | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | | | | | | | | | | | ✓ | | | | |
| **13. POWDERED GLOVE SLURRY** - antimicrobial; Surfactants; Ingredients; Temperature; Amount used; Agitation; Microbial growth; Clean out frequency **(3)** | ✓ | ✓ | ✓ | | | | | ✓ | ✓ | | ✓ | | | | | | | | ✓ | ✓ | ✓ | | | |
| **14. CHLORINATION POWDER FREE GLOVES** - Concentration; Filtration; Duration; Load; Reversals; pH; Agitation; Drain efficacy and speed; Neutralization; Rinse Quality | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | | | ✓ | ✓ | | ✓ | | |
| **15. LUBRICANT** - Type; Concentration; Distribution; Microbial Growth | ✓ | ✓ | | | | | ✓ | ✓ | ✓ | | | | ✓ | | | | | | ✓ | ✓ | ✓ | | | |
| **16. DRYERS** - Delay; Temperature; Duration; Cross Contamination; Humidity; Filtration; Load / Space; Airflow | ✓ | | | ✓ | ✓ | | | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | | ✓ | ✓ | ✓ | ✓ | | |
| **17. PACKAGING** - Line Clear; Clean up; Label control; Packaging material; Stack method; Sun / light exposure | | | ✓ | ✓ | ✓ | | | | | ✓ | ✓ | ✓ | | | | | | | ✓ | ✓ | ✓ | | | |
| **18. TRANSPORT / STORAGE** - Temperature; Moisture; Protection; Insulation | ✓ | | | ✓ | ✓ | | | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | | ✓ | ✓ | ✓ | | | |
| **19. CLEANING - HOW? WHEN?** - Formers; Filters / Screens; Tanks; Mop (no sweeping); Air / Surface; Line Change; Personnel; Chain guards | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | ✓ | | ✓ | | | | | | | ✓ | ✓ | ✓ | | | |
| **20. COATINGS** - Laminates, Bound polymers **(4)** | ✓ | ✓ | | | | | ✓ | | | ✓ | | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | | | | ✓ | | |
| **21. EXTRACT TREATMENTS** - Enzymes, Protein binders | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | ✓ | | ✓ | | | | | | | | | | | | |
| **22. Other** (Add for your glove and processes) | | | | | | | | | | | | | | | | | | | | | | | | |

GRZAN

## EXHIBIT #5 MONITORING AND PROCESS PARAMETER CONTROL RECORD

SAMPLE ******* Do not use without modifying to meet your specific needs. *******

**MACHINE DIP LINE PARAMETERS PER DAY**

LINE: _____ SHIFT: _____ DATE: _____

OPERATOR: _____ SUPERVISOR: _____

| **ITEM OR PROCESS TAKEN** | **TIME & PARAMETER** | | | **ACTION** |
|---|---|---|---|---|
| 1. Acid tank 55-60$^0$ C. | | | | |
| Level | | | | |
| 2. Rinse 45-50$^0$ C. | | | | |
| Level | | | | |
| 3. Water 55-60$^0$ C. | | | | |
| Level | | | | |
| 4. Wash oven 80-85$^0$ C. | | | | |
| 5. Coagulant 50-55$^0$ C. | | | | |
| Level | | | | |
| 6 Coagulant oven 80-85$^0$ C | | | | |
| 7. Latex dip 27-29$^0$ C. | | | | |
| Level | | | | |
| 8. Tack oven 85-90$^0$ C. | | | | |
| 9. Beading | | | | |
| 10. Leaching 55-65$^0$ C. | | | | |
| (1) Level in tank | | | | |
| 11. Leaching 55-65$^0$ C. | | | | |
| (2) Level in tank | | | | |
| 12. Cure oven #1 temp. | | | | |
| 13. Cure oven #2 temp. | | | | |
| 14. Cure oven #3 temp. | | | | |
| 15. Protein Rinse operating | | | | |
| Chain speed | | | | |
| Line start time | | | | |
| Line stop time | | | | |
| ~ items produced / hour | | | | |
| Length of glove (23-24 cm) | | | | |
| Weight of glove (gm) | | | | |
| Reject weight (kg) | | | | |
| Remarks | | | | |

# 9 COMPLIANCE ACTIVITIES


| | |
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## FACTORY INSPECTIONS

FDA evaluates manufacturer compliance with the medical device regulations primarily by factory inspections. During the inspection, the FDA investigator will review your facilities, design controls (for surgeon's gloves), manufacturing operations, environment, and records to determine your level of compliance. The emphasis will be on compliance with the Quality System regulation (21 CFR part 820). The FDA inspection program includes foreign manufacturing sites. FDA will contact foreign firms to schedule an inspection.
You will find guidance on how FDA conducts factory inspections, including regulatory sanctions FDA can take against noncompliant firms, in the following guidance documents.

> Factory Inspections (Medical Device Quality Systems Manual: A Small Entity Compliance Guide)
> http://www.fda.gov/cdrh/qsr/18inspn.html
>
> Quality System Inspection Technique (QSIT)
> http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm

## IMPORTING GLOVES AND FDA SAMPLING

You will find information on the FDA import process at http://www.fda.gov/cdrh/devadvice/39i.html. FDA may collect a sample of your gloves and test the gloves in accordance with 21 CFR 800.20, "Patient examination gloves and surgeon's gloves; sample plans and test method for leakage defects; adulteration." Sketches of the test apparatus described in 21 CFR 800.20 are provided in Appendix A.

When a glove shipment includes multiple lots or sizes, it is considered a commingled shipment. FDA usually will not sample each individual lot within a commingled shipment. In the sample, FDA will include only one type of glove (surgeon's gloves or examination gloves) and will attempt to represent glove sizes in the sample as they occur in the overall shipment. Also, FDA will attempt to include several lot numbers, if present. However, exact proportional representation of all lots or sizes is not necessary to obtain a representative sample for testing. A shipment of gloves may be refused entry based on the appearance of adulteration (Section 801 of the Act; 21 U.S.C. 381), and such an appearance can be obtained even if the sample includes only one lot number or one size. If the sample fails, FDA will

detain all lots of the same glove type (surgeon's gloves or examination gloves) in the shipment.

FDA provides its sampling methodology and defect action levels in the FDA Compliance Policy Guide, Chapter 3, Section 335.700, *Surgeon's Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure*.

> CPG 335.700 Surgeon's Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure (CPG 7124.31)
> http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg335-700.html

## COMPLIANCE ACTIVITIES

FDA may pursue regulatory sanctions when medical devices are determined to be "adulterated" or "misbranded," or when individuals or firms commit certain "prohibited acts." (Sections 301, 501, and 502 of the Act; 21 U.S.C. 331, 351, and 352.) These generic terms also apply to other products that FDA regulates, such as foods, drugs, and cosmetics; however, the causes of adulteration and misbranding are not identical for all products. The following summarizes some common reasons why FDA may consider medical gloves to be adulterated or misbranded.

### Adulteration

Generally, a charge of adulteration indicates a potentially serious problem with the medical device itself. Section 501 of the Act describes possible reasons for adulteration. Several common examples of adulterated medical gloves are:

- Gloves that do not provide an intact barrier as evidenced by failure of a water leak test (21 CFR 800.20). The gloves are adulterated according to section 501(c) - failure of the gloves to have the quality that they are represented to have.

- Gloves that have never been cleared to market are automatically classified in Class III (section 513(f)(1) of the Act). Without clearance or approval, the gloves are adulterated according to section 501(f)(1)(B)(i).

- Gloves that have been manufactured, packaged, or stored in a facility that was inspected by FDA and that was found not in conformity with the Quality System regulation (21 CFR part 820). The gloves are adulterated according to section 501(h) because the facilities and controls used for manufacturing, packing, and storage do not meet GMPs as described in the Quality System regulation (21 CFR 820).

## Misbranding

Usually, a charge of misbranding indicates a problem with the labeling or documentation of the device or device manufacturer. Section 502 of the Act describes possible reasons for misbranding. Several common examples of misbranded medical gloves are:

- Gloves that have exaggerated, untrue, or unsubstantiated claims are "misbranded" under section 502(a) of the Act, because the labeling is false or misleading in some manner. Examples of claims that may misbrand a medical glove include:
    - "Leak Proof" or similar unsupportable claims of performance
    - "Hypoallergenic" claims for latex gloves (prohibited by 21 CFR 801.437(h))
    - "Antimicrobial" claims without supporting data
    - "Accelerator Free"
    - "Skin Care" claims without supporting data
    - "Synthetic Gloves" that do not identify the material
    - "Low Protein" claims that do not quantify the amount of protein
    - "Extra Thick" claims that do not quantify the thickness
    - "Lightly Powdered" claims
- Natural rubber latex gloves that do not include the latex "Caution" statement required by 21 CFR 801.437. These gloves are misbranded under section 502(a) because the labeling fails to reveal important information about the use of the product as required by section 201(n).
- Gloves that are not labeled with the name of the manufacturer or distributor are misbranded according to section 502(b).
- Disposable gloves that are not labeled with a statement "For single use only" are misbranded according to section 502(f)(1) for failure to have adequate directions for use.
- Gloves that do not meet applicable registration and listing requirements are misbranded according to section 502(o).

### Disposition of Adulterated or Misbranded gloves

If any lots of medical gloves are found to be adulterated or misbranded, the manufacturer or importer of record may request to recondition the gloves to bring them into compliance (see 21 CFR 800.20(d)).

The importer of record should advise the FDA District Office that initiated the detention of the firm's plans to bring the product into compliance. If the gloves cannot be brought into compliance, they cannot be marketed in the U.S. as medical gloves.

**Non-conforming medical gloves may be brought into conformance by:**

- reconditioning to correct the non-conformance, i.e., remove defective gloves, correct labeling deficiencies; or
- reconditioning by relabeling, and subsequently distributing the gloves for non-medical use, or non-FDA regulated use.

A manufacturer/importer that chooses to recondition the product should request and obtain permission from the responsible FDA District Office.

The importer of record may also request permission to recondition a commingled shipment that has failed FDA analysis by testing each lot or size in the shipment to identify whether some lots or sizes meet the specified acceptable quality levels. Because the original analysis provides an appearance of adulteration, FDA will need greater assurance that the reconditioned gloves are not adulterated. The importer should consult with the FDA District Office to obtain the appropriate sampling plan. Only those lots/sizes that are shown to be in compliance, subject to verification testing by FDA, can be released for distribution in the U.S.

If nonconforming medical gloves cannot be reconditioned, the medical gloves should be

- re-exported to the country of manufacture or to a country where the gloves would meet local laws, or
- destroyed, usually via landfill.

## DETENTION

### Detention

Detention is the action that FDA takes against imported medical devices that do not comply with the laws that FDA administers (21 CFR 800.55)). FDA may detain imported medical devices whenever physical examination or testing of a medical device, or examination of medical device labeling and labeling claims by FDA show that the medical device violates FDA laws. The importer of record may file an appeal requesting an informal hearing. A presiding FDA officer will affirm or revoke the detention. Detained devices are either released if brought into compliance or refused entry if not brought into compliance.

### Detention Without Physical Examination

Detention Without Physical Examination (DWPE) is the act by FDA of detaining the entry of a specified article, usually from a specific supplier, and occasionally from all suppliers from a specific country, without physical examination or testing. DWPE differs from general administrative detention in that it is imposed based on the previous violative history of an imported medical device being offered for entry into the U.S. DWPE does not occur as a result of a violative analysis or evaluation of the present entry found by FDA. DWPE is an action used for repeat violations or violators. DWPE essentially places the responsibility for

determining quality and compliance with the law upon the U.S. importer or broker, and indirectly upon the foreign supplier (or sometimes a country). DWPE is generally based on information regarding the past violative history of the medical device and/or other information indicating that the medical device may be violative.

DWPE actions are implemented through the issuance of FDA "Import Alerts." A list of medical glove related FDA Import Alerts is provided below:

**IMPORT ALERTS FOR MEDICAL GLOVES**

There are currently several import alerts under which medical gloves are commonly refused entry. Import alerts provide the reason for the alert and provide information on how to be removed from the alert:

- Import Alert #80-04, "Surveillance and Detention without Physical Examination of Surgeon's and/or Patient Examination Gloves."
  http://www.fda.gov/ora/fiars/ora_import_ia8004.html

  Manufacturers/shippers placed on this alert have had at least one previous failure of their gloves to pass an FDA analysis. This import alert consists of three increasingly more stringent levels of detention for manufacturers/shippers who repeatedly attempt to import adulterated gloves (Recidivist Firms).

- Import Alert #89-04, "Detention without Physical Examination of Devices that have not met Device GMPs."
  http://www.fda.gov/ora/fiars/ora_import_ia8904.html

  Manufacturers/shippers placed on this alert have had a violative FDA inspection and are not manufacturing in accordance with Quality System regulation. Manufacturers may be removed from the alert after an FDA inspection has verified corrective action.

- Import Alert #89-08, "Detention without Physical Examination of Class III Medical Devices Without Approved PMAs/IDEs or Other Devices Not Found Substantially Equivalent."
  http://www.fda.gov/ora/fiars/ora_import_ia8908.html

  Manufacturers/shippers placed on this alert do not have a cleared 510(k) for their gloves. Manufacturers may have their gloves removed from the alert after they receive a 510(k) marketing clearance letter for the specific glove type (powdered, powder-free, vinyl, etc.).

Importers may contact FDA near the port of entry and speak to the import operations staff regarding their entry. Callers should have their entry numbers available for reference.

FDA Field Offices
http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html

More information regarding DWPE of gloves, including information regarding removal from DWPE, may be found in the FDA guidance, "Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves." [1]

[1] At the time this guidance was issued, the guidance on "Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves" was in draft status.

## APPENDIX A - SUGGESTED GLOVE TESTING APPARATUS

Fig 1

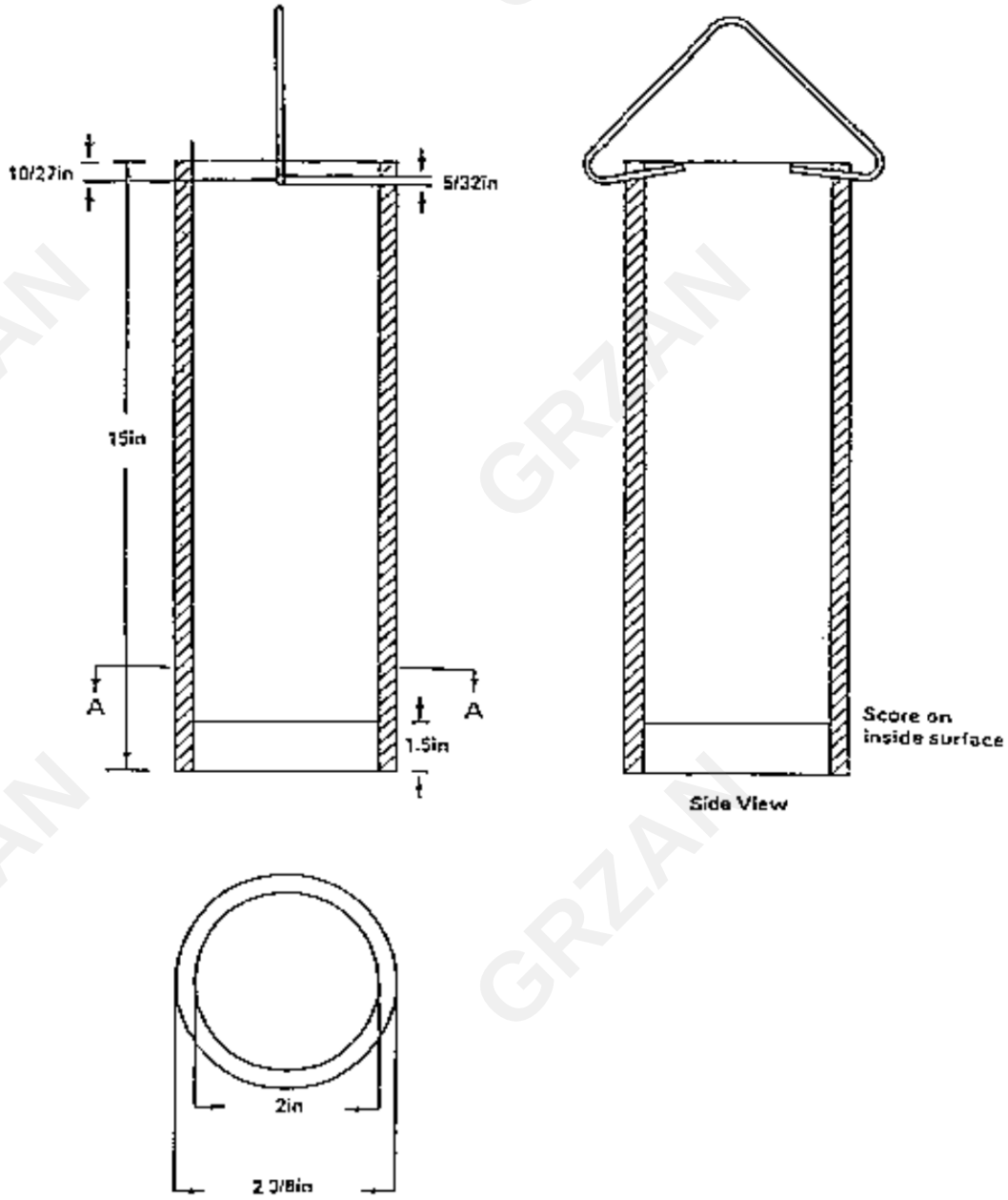
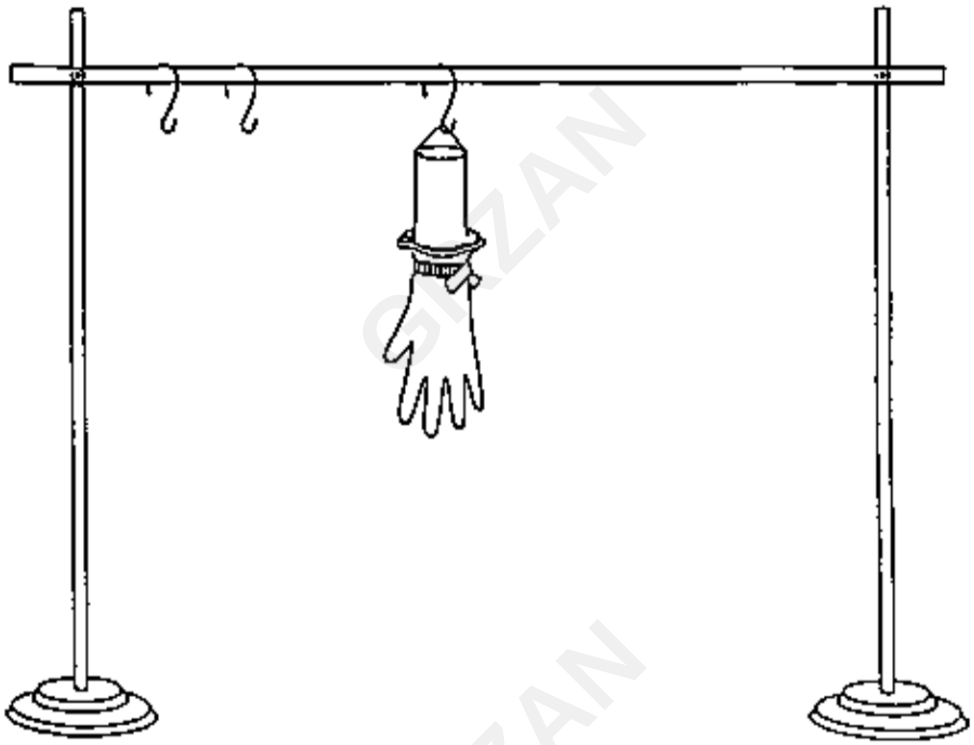


Fig 2



# 10 VOLUNTARY STANDARDS

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## INTRODUCTION

Conformance with recognized consensus standards can help provide a reasonable assurance of safety and/or effectiveness for many aspects of medical devices. Conformance to consensus standards is voluntary and may be used to demonstrate performance or safety of a device.

## FDA-RECOGNIZED CONSENSUS STANDARDS

Conformance with consensus standards will help establish the equivalence of a new glove to a legally marketed predicate glove in a Premarket Notification 510(k) submission. If a person elects to use a standard recognized by FDA to meet a premarket submission requirement (or other requirement under the Act to which such standard is applicable), the person must provide a declaration of conformity to the FDA that certifies the device is in conformity with the standard (section 514(c)(1)(B) of the Act (21 USC 360d(c)(1)(B)). At any time, FDA may request the data or information relied on by the person to make a declaration of conformity (section 514(c)(3)(B)). A person making a declaration of conformity must maintain the data and information demonstrating conformity for a period of two years after the date of the classification or approval of the device by FDA or a period equal to the expected design life of the device, whichever is longer (514(c)(3)(C)).

The manufacturer should submit the declaration of conformity in the Abbreviated 510(k) method. Consensus standards may also be used in the Traditional 510(k) method to help establish equivalence. See FDA guidances "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" (http://www.fda.gov/cdrh/ode/parad510.html) and "Use of Standards in Substantial Equivalence Determinations" (http://www.fda.gov/cdrh/ode/guidance/1131.html for additional information on the use of consensus standards in 510(k) submissions.

Information on FDA's standard program, including a database of FDA-recognized standards, can be found on the following website:

CDRH Standards Program
http://www.fda.gov/cdrh/stdsprog.html

At this time FDA recognizes the following standards:

**Patient Examination Gloves**

| | | |
|---|---|---|
| ASTM | D5151 | Standard Test Method for Detection of Holes in Medical Gloves |
| ASTM | D6319 | Standard Specification for Nitrile Examination Gloves for Medical Application |
| ASTM | D6124 | Standard Test Method for Residual Powder on Medical Gloves |
| ASTM | D5250 | Standard Specification for Poly(vinyl chloride) Gloves for Medical Application |
| ASTM | D3578 | Standard Specification for Rubber Examination Gloves |
| ASTM | D3772 | Standard Specification for Rubber Finger Cots |

**Surgeon's Gloves**

| | | |
|---|---|---|
| ASTM | D5151 | Standard Test Method for Detection of Holes in Medical Gloves |
| ASTM | D6124 | Standard Test Method for Residual Powder on Medical Gloves |
| ASTM | D3577 | Standard Specification for Rubber Surgical Gloves |

**Test Methods**

| | | |
|---|---|---|
| ASTM | D5712 | Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method |
| ASTM | D6499 | Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products |
| ASTM | D5151 | Standard Test Method for Detection of Holes in Medical Gloves |
| ASTM | D6124 | Standard Test Method for Residual Powder on Medical Gloves |

You can find current FDA-recognized standards in the CDRH standards database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Search.cfm

**OTHER CONSENSUS STANDARDS**

In addition to FDA-recognized standards, manufacturers may use other consensus standards. As discussed earlier, under the Act, only FDA-recognized standards are those for which you may submit a declaration of conformity in order to meet a premarket requirement; however, you may find other consensus standards that have not been recognized by FDA useful. Below is a list of some of the standards applicable to medical gloves.

## Glove Standards

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|---|---|
| ANSI/ADA76 | Non-sterile latex gloves for dentistry. |
| ADA Spec No. 102 | Non-sterile nitrile gloves for dentistry. |
| ASTM D5250 | Standard specification for poly(vinyl chloride) gloves for medical application. |
| ASTM draft | Standard specification for nitrile examination gloves for medical application. |
| ISO10282 | Single-use surgical rubber gloves-Specification. |
| ISO11193 | Single-use rubber examination gloves-Specification. |
| AS/NZS 4011 | Single-use examination gloves—specification. |
| EN 455-1 | Medical gloves for single use. Part 1. Specification for freedom from holes. |
| EN 455-2 | Medical gloves for single use. Part 2. Specification for physical properties. |
| CAN 20.27-M91 | Sterile or non-sterile medical examination gloves for single use. |
| MS1155 | Malaysian standard for rubber examination glove. |
| JIS T 9107 | Japanese Industrial Standard. Surgical gloves. |

## Test Standards

| | |
|---|---|
| ASTM D412 | Test methods for vulcanized rubber and thermoplastic rubbers and thermoplastic elastomers—tension. |
| ASTM D573 | Test method for rubber—deterioration in an air oven. |
| ASTM D3767 | Practice for Rubber—measurement of dimensions. |
| ISO 2859 | Sampling procedures and tables for inspection by attributes. |
| ISO 37-94 | Method for determination of tensile stress-strain properties (to determine the force at break) |
| ISO 188 | Heat resistance and accelerated aging tests. |
| ISO 4648 | Physical testing of rubber. Methods for the determination of dimensions of test pieces and products for test purpose. |

## Expiration Dating

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|---|---|
| ASTM D7160 | Standard Practice for Determination of Expiration Dating for Medical Gloves |
| ASTM D7161 | Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions |

## Standard Organizations

| | |
|---|---|
| ADA | American Dental Association |
| ANSI | American National Standards Institute |

| | |
|---|---|
| ASTM | ASTM International |
| CAN | National Standard of Canada |
| EN | European Standard |
| ISO | International Standard |

Each manufacturer that distributes patient examination or surgeon's gloves in the U.S. should have in its files at the manufacturing site an original copy of each pertinent standard referenced by the manufacturer's Quality System device master record(s) and/or 510(k) submission(s). During an inspection, the FDA investigator may ask to see a copy of each referenced standard and any data demonstrating that the gloves conform to the standard.

You may purchase standards from the following organizations.

ANSI
11 West 42nd Street
New York, New York 10036
Phone: 212-642-4900
Fax: 212-398-0023
http://www.ansi.org/

ASTM International
100 Barr Harbor Drive,
West Conshohocken, PA19428-2959
Phone: (610) 832-9585
Fax: (610) 832-9555
http://www.astm.org