



American National Standard/  
American Dental Association  
**Specification No. 103**

# Non-Sterile Poly Vinyl Chloride Gloves for Dentistry

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**ADA** American  
Dental  
Association®  
Council on  
Scientific Affairs

This is a preview of "ANSI/ADA 103-2001 (R...)". [Click here to purchase the full version from the ANSI store.](#)

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION  
SPECIFICATION NO. 103 FOR NON-STERILE POLY VINYL CHLORIDE  
GLOVES FOR DENTISTRY**

American Dental Association Specification No. 103 for Non-Sterile Poly Vinyl Chloride Gloves for Dentistry has been approved by the Council on Scientific Affairs of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment. The Council acts as administrative sponsor of that committee, which has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. Approval of ADA Specification No. 103 as an American National Standard was granted by the American National Standards Institute on January 4, 1999. This standard becomes effective January 4, 2000.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Tom Tillotson (Chairman), Tillotson Healthcare Corp., Bedford, NH; Jason Baker, Microflex Medical, Reno, NV; Andreas Brown, Preventive Care, Eagan, MN; P.L. Fan, American Dental Association, Chicago, IL; Michael Garrobo, Best Manufacturing, Menlo, GA; Charles B. Hermes, University of Texas Health Science Center, San Antonio; Judith Hill, USAF; Margaret Marsh, Johnson & Johnson Medical, Arlington, TX; Bill Morris, Allegiance Healthcare Corp., McGaw Park, IL; Brad J. Ploeger, Clinical Research Associates, Provo, UT; Ruthlyn Reyes, Safeskin Corp., San Diego, CA; Shannon Mills, Robins AFB, GA; Anita Shoup, Steve Esposito, and Jeff Kitzmiller for Herb Adams, Regent Medical, Norcross, GA; Michael J. Stefanson, Quantum Labs, Minneapolis, MN; Kim Sullivan, SmartPractice, Phoenix, AZ; and Terrance Thines, SUNYAB School of Medicine, Buffalo, NY.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION  
NO. 103 FOR NON-STERILE POLY VINYL CHLORIDE GLOVES FOR DENTISTRY**

**FOREWORD**

This new ANSI/ADA Specification is intended for gloves made from Poly Vinyl Chloride, commonly known as PVC or Vinyl that are designed and labeled specifically for dentistry.

Because of the non-stretch properties of PVC, dimensions of gloves are different than natural rubber latex. As there is minimal stretch, sizing is generally larger per size than natural rubber latex gloves.

This specification is meant to conform to the American Society of Testing and Materials standard specification for vinyl gloves D5250-92, Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Application. To this, Specification No. 103 has added requirements for claims of powder-free and additional labeling that is of specific use to dentistry.

## AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 103 FOR NON-STERILE POLY VINYL CHLORIDE GLOVES FOR DENTISTRY

### 1. SCOPE

This specification covers non-sterile poly vinyl chloride gloves suitable for dentistry.

**Note 1:** The limitations of these gloves should be considered where barrier properties could be compromised due to extended wear situations or where good tactile perception is necessary.

### 2. APPLICABLE DOCUMENTS

#### 2.1 ASTM Standards:

D412, Tests for Rubber Properties in Tension

D573, Test for Rubber Deterioration in an Air Oven

D3578, Standard Specification for Rubber Examination Gloves

D3767, Practice for Rubber—Measurements of Dimensions

D5151, Test Method for Detection of Holes in Medical Gloves

D5250-92, Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Application

D6124, Test Method for the Determination of Powder Content in Gloves

#### 2.2 Other Documents:

ISO 2859, Sampling Procedures for Tables for Inspection by Attributes

ISO 10993-10/ASTM F720, Standard Practice for Testing Guinea Pigs for Contact Allergens—Guinea Pig Maximization Test

ISO 10993-10/ASTM F719, Standard Procedure for Testing Biomaterials in Rabbits for Primary Skin Irritation

(ISO Standards and other ANSI/ADA Specifications are available from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036).

21CFR Part 820, Good Manufacturing Practices (GMPs) for Medical Devices (regulation of the U.S. Food and Drug Administration)

### 3. MATERIALS AND CONSTRUCTION

3.1 Any poly (vinyl chloride) polymer compound may be used that permits the glove to meet the requirements of this standard. This specification does not cover two-dimensional, heat-sealed plastic gloves.

3.2 Gloves shall have been tested for biocompatibility using ISO 10993-10/ASTM F720, Standard Practice for Testing Guinea Pigs for Contact Allergens—Guinea Pig Maximization Test, and ISO 10993-10/ASTM F719, Standard Procedure for Testing Biomaterials in Rabbits for Primary Skin Irritation.