



American National Standard/
American Dental Association
Specification No. 102

Non-Sterile Nitrile Gloves for Dentistry

ADA American
Dental
Association®
Council on
Scientific Affairs

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 102 FOR NON-STERILE NITRILE GLOVES FOR DENTISTRY

American Dental Association Specification No. 102 for Non-Sterile Nitrile 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. 102 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.

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FOREWORD

This ANSI/ADA specification is intended for gloves designed and labeled specifically for dentistry made from poly butadiene-acrylonitrile, commonly known as nitrile.

Nitrile gloves have now been used in dentistry for several years. Low modulus versions tend to reduce hand fatigue. All versions are free of the natural rubber latex proteins that are a problem for some users. Because nitrile is an elastomer, it can provide the barrier protection required in dentistry while at the same time providing good tactile sense.

Because of the conforming properties of nitrile, dimensions of gloves are different than natural rubber latex. As dentistry requires maximum tactile perception, sizing is slightly smaller per size than natural rubber latex. In addition, this conforming feature allows a glove to be sized to cover more than one size, thus reducing inventory costs.

Addendum to the Foreword for this Reaffirmation:

In 2012, the ADA Standards Committee on Dental Products approved a change in the terminology used for standards. ADA standards will no longer utilize the term Specification; standards will now be named as ADA Standards.

With this notice, this ADA Specification is now termed an ADA Standard. Where the term "specification" is used, it should be considered as "standard." It will be re-named as an ADA Standard in its next revision.

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1 SCOPE

This specification covers non-sterile nitrile gloves suitable for dentistry that do not contain any natural rubber latex.

2 APPLICABLE DOCUMENTS

2.1 ASTM Standards:

D412, Tests for Rubber Properties in Tension

D573, Test for Rubber Deterioration in an Air Oven

D6319, Standard Specification for Nitrile Rubber Examination Gloves

D3767, Practice for Rubber—Measurements of Dimensions

D5151, Test Method for Detection of Holes in Medical Gloves

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 Procedure for Testing Biomaterials in 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).

3 MATERIALS

3.1 Any nitrile rubber polymer compound may be used that permits the glove to meet the requirements of this standard and provide barrier protection to biohazards.

3.2 Gloves shall have been tested for biocompatibility using ISO 10993-10/ASTM F720 and ISO 10993-10/ASTM F719.

4 REQUIREMENTS

4.1 Dimensions

Gloves shall meet an Acceptable Quality Level (AQL) of 4.0.

4.1.1 Width by size

The dimensions shall be as shown in Table 1 with a tolerance of ± 6 mm allowed when tested as specified in 6.2.