ANSI/ADA Specification No. 76-2005
Reaffirmed by ANSI: October 26, 2015

American National Standard/
American Dental Association

Specification No. 76

Non-Sterile Natural Rubber Latex Gloves for Dentistry

ADA American Dental Association®
Council on Scientific Affairs

2005

ANSI/ADA Specification No. 76 – 2005
Reaffirmed: October 2015

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 76 FOR NON-STERILE NATURAL RUBBER LATEX GLOVES FOR DENTISTRY

American Dental Association Specification No. 76 for Non-Sterile Natural Rubber Latex 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 American Dental Association Standards Committees on Dental Products. The Committee 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. 76 as an American National Standard was granted by the American National Standards Institute on June 15, 2005. This standard becomes effective June 15, 2006.

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), Healthco International, LLC., Dixville Notch, NH; Andreas Brown, Preventive Care, Eagan, MN; P.L. Fan and Chakwan Siew, American Dental Association, Chicago, IL; Don Groce, Best Manufacturing, Menlo, GA; Charles B. Hermesch, University of Texas Health Science Center, San Antonio; Jarvis T Chan, University of Texas Health Science Center, Houston; Bill Morris, Baxter Healthcare Corp., Round Lake, IL; Wava Truscott, Kimberly-Clark Health Care, Roswell, GA; Shannon Mills, USAF; Herb Adams, Regent Medical, Norcross, GA; Michael J. Stefanson, Quantum Labs, Minneapolis, MN; Kim Sullivan, SmartPractice, Phoenix, AZ; Doug Beck, Cardinal Healthcare, McGaw Park, IL; Donald Chu, Tronex Healthcare, Denville, NJ; Mark Heiss, Bisco Dental, Schaumburg, IL; Patrick McCrann, Prostat Inc., Middlesex, NJ; Darren Soon Tan, Malaytex USA, American Canyon, CA; and Terrance Thines, SUNYAB School of Medicine, Buffalo, NY.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 76 FOR NON-STERILE NATURAL RUBBER LATEX GLOVES FOR DENTISTRY

FOREWORD

(This foreword is not a part of the ANSI/ADA Specification No. 76 for Non-Sterile Natural Rubber Latex Gloves for Dentistry).

This revision of ANSI/ADA Specification No. 76, Non-Sterile Natural Rubber Latex Gloves for Dentistry, is designed to bring it into conformance with revisions to ASTM standards that have occurred since it was revised in 1999. These changes are embodied in ASTM D3578-03, Standard Specification for Rubber Examination Gloves.

Principal among these are changes to the allowable number of water leak defects and the inclusion of maximum powder limits for powdered gloves and maximum protein limits for both powdered and powder free gloves.

The standard for maximum allowable water leaks was reduced from 4% to 2.5% to reflect the increased capability of the industry to produce gloves with improved barrier protection.

To minimize the risk of contamination from fugitive particulates when using powdered gloves, a revised powder level test has been included in ASTM D6124 and a phased in limit of 10 mg/dm^2 has been established.

A new test for antigenic proteins, ASTM D6499, has been adopted by ASTM and a limit of 10mg/dm^2 has been established as an alternative to the ASTM D5712 protein test limit of 200 $\mu g/dm^2$ for total protein. The inclusion of this more precise test allows manufacturers to focus on reduction of antigenic proteins beyond the test limits of the current test.

Finally, sampling methods for protein and powder testing are revised to provide a better statistical basis for the interpretation of results for these tests.

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.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 76 FOR NON-STERILE NATURAL RUBBER LATEX GLOVES FOR DENTISTRY

1 SCOPE

1.1 This specification covers non-sterile natural rubber latex gloves suitable for dentistry.

2 APPLICABLE DOCUMENTS

2.1 ASTM Standards (most current version unless otherwise specified)

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

D5712 Standard Test Method for Analysis of Protein in Natural Rubber Latex and Its Products

D6124 Test method for the Determination of Powder Content in Gloves

D6499 ELISA Inhibition Test Method for Antigenic Proteins in Medical Gloves

(ASTM Standards are available from the American Society of Testing and Materials, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428).

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 Maximuzation Test

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

(ISO Standards are available from the American National Standards Institute, 25 West 43rd Street, New York, NY 10036).

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

3 MATERIALS AND CONSTRUCTION

3.1 Any compound that contains natural rubber latex may be used that permits the glove to meet the requirements of this standard.