12 VOLUNTARY STANDARDS

INTRODUCTION TO STANDARDS

Many domestic and international consensus standards address aspects of safety and/or effectiveness relevant to medical devices. Many of these standards were developed with the participation of CDRH staff.

For more information on the use of standards by CDRH, please see http://www.fda.gov/cdrh/stdsprog.html or phone CDRH Facts On Demand at 1-800-899-0381 or 301-827-0111 and specify #321 when prompted for the document shelf number.

CDRH believes that conformance with consensus standards can provide a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices. Therefore, information submitted on conformance with such standards will have a direct bearing on safety and effectiveness determinations. In the case of 510(k) submissions for gloves, information on conformance with consensus standards will help establish the equivalence of a new glove to a legally marketed predicate glove for the parameters or areas covered by the standards the manufacturer is meeting.

USE OF GLOVE RELATED STANDARDS

FDA relies on the voluntary standards issued by the American Society for Testing and Materials (ASTM) D 3578, D 3772 (finger cots), D 5250 for the parameters of patient examination gloves and D 3577 for surgeon's gloves. The ASTM website is: http://www.astm.org. ASTM D 5712 covers the *Standard Test Method for the Analysis of Protein in Natural Rubber and Its Products.*

ASTM D 6124 covers the *Standard Test Method for Residual Powder on Medical Gloves.*

ASTM standards are available from:

American Society for Testing and Materials
100 Barr Harbor Drive
West Conshohocken PA 19428 USA
Phone: 610-832-9500 FAX: 610-832-9555

ASTM standards are also available from:

Singapore Productivity Board
1, Science Park Drive
Singapore 118221
Phone: 65-278-6666 FAX: 65-278-6665 Website: http://www.psb.gov.sg

The ASTM standard for each type of glove is noted in appropriate sections of this manual.

Each manufacturer that distributes patient examination or surgeon's gloves in the U.S. should have an original copy of each ASTM or equivalent standard on file referred to by the manufacturer's QS 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.

Manufacturers that want to perform tests for particulates, extractable materials, chemical resistance, bioburden, etc., may refer to IES-RP-CC-005-87-T for *Cleanroom Gloves and Finger Cots.* This standard is available from:

Institute of Environmental Sciences
940 East Northwest Highway
Mount Prospect, Illinois 60056 USA
Phone 708-255-1561

The following pages present tables of selected data from glove standards around the world. The information presented here is not complete and interested readers should refer to a current copy of the standard for official parameters and other pertinent information.

This information is provided for your reference. The United States FDA may not recognize these standards in whole or in part. Information regarding the glove standards which the FDA does recognize is found elsewhere in this chapter.

The presence or absence of a standard in these tables does *not* indicate FDA recognition or disapproval of any particular standard.

Latex Patient Examination Glove Standards

		Physical dimension					Physical property				other requirements	sampling plan			
		minimum length (mm)		width range (mm)	minimum thickness (mm)		minimum tensile strength (Mpa)		minimum % elongation						
standards	sizes	seam	un seam	min -- max	smooth	textured	before aging	after aging	before aging	after aging		scope	ref	level	AQL
ADA ADA76-91	small medium large	230 230 230		70 -- 90 85 -- 105 101 -- 121	0.08 0.08 0.08		21	16	700%	500%	holes: follow ASTM D5151	dimension physical	ISO 2859	II II	4.0 4.0
ASTM D3578-99	small unisize medium large	220 220 230 230		70 -- 90 75 -- 95 85 -- 105 101 -- 121	0.08 0.08 0.08 0.08		14	14	700%	500%	holes: follow ASTM D5151	dimension physical holes	ISO 2859	S-2 S-2 I	4.0 4.0 2.5
ISO ISO 11193-94	small medium large	230 230 230		70 -- 90 85 -- 105 101 -- 121	0.08 0.08 0.08	0.11 0.11 0.11	21	15	700%	500%		dimension physical holes	ISO 2859	S-2 S-2 S-4	4.0 4.0 2.5
European EN 455-2-95	small medium large	270 270 270	240 240 240	70 -- 90 85 -- 105 100 -- 120			before aging 7.5 newtons after aging 5.5 newtons				holes: follow EN455-1-95	all	ISO 2859	S-2	4
Australian/ New Zealand AS/NZS 4011-97	small medium large	230 230 230		70 -- 90 85 -- 105 100 -- 120	0.08 0.08 0.08	0.11 0.11 0.11	21	16	700%	500%	holes: Appendix B rupture resistance: Appendix C	dimension physical holes	ISO 2859	S-2 S-2 S-4	4.0 4.0 2.5
Canadian CAN20.27-M91	small unisize medium large	230 230 230 230		80 -- 90 85 -- 105 90 -- 100 100 -- 120	0.08 0.08 0.08 0.08		16	16	500%	500%	visible hole and contamination detection inspection	dimension physical visible holes	ISO 2859	S-2 S-2 S-2 I	major defects 4.0 minor defects 6.5

Malaysian MSG	small medium large	230 230 230	70 -- 90 85 -- 105 101 -- 121	0.08 0.08 0.08	21	16	700%	500%		dimension physical holes	ISO 2859	S-2 S-2 2	4.0 4.0 4.0

latex exam glove standards //ltx exm glv std

Synthetic Material Patient Examination Glove Standards

		physical dimension				physical property					sampling plan			
		minimum length (mm)		width range (mm)	minimum thickness (mm)	minimum tensile strength (Mpa)		minimum % elongation		other requirements				
standards	sizes	seam	un seam	min -- max		before aging	after aging	before aging	after aging		scope	ref	level	AQL
ADA* ADA No. 102 nitrile	small unisize medium large	220 230 230 230		70 – 90 75 – 95 85 – 105 95 -- 115	0.08 0.08 0.08 0.08	12.5	12	500%	400%	holes: follow ASTM 5151 powder: follow ASTM 6124	dimension physical holes	ISO 2859	S-2 S-2 G-2	4.0 4.0 4.0
ASTM D5250-99 PVC	small medium large	220 230 230		80 – 90 90 – 100 100 – 110	0.08 0.08 0.08	9		300%		holes: follow ASTM D5151 free of talc	dimension physical holes	ISO 2859	S-2 S-2 I	4.0 4.0 2.5
ASTM* draft nitrile	small unisize medium large	220 220 230 230		70 – 90 75 – 95 80 – 90 90 -- 110	0.08 0.08 0.08 0.08	12.5		500%	400%	holes: follow ASTM D5151 free of talc	dimension physical holes	ISO 2859	S-2 S-2 S-4	4.0 4.0 4.0
European EN455-2-95 synthetic	small medium large	270 270 270	240 240 270	70 -- 90 85 -- 105 100 -- 120		3 newtons				holes: follow EN455-1-95	all	ISO 2859	S-2	4
Australian/ New Zealand AS/NZS 4011-97 synthetic	small medium large	230 230 230		70 -- 90 85 -- 105 100 -- 120	0.08 0.08 0.08	synthetic: 12 Mpa PVC: 9 MPa		300% 280%		holes: Appendix B rupture resistance: Appendix C	dimension physical holes	ISO 2859	S-2 S-2 S-4	4.0 4.0 2.5

* : draft standard

Synthetic Examination Glove Standards syn exm glv std

Latex Surgical Glove Standards

Standards	Sizes	Physical dimension				Physical property				Other requirements	Sampling plan			
		minimum length (mm)	width range (mm)	minimum thickness (mm)		minimum tensile strength (Mpa)		minimum % elongation						
			min -- max	smooth	textured	before aging	after aging	before aging	after aging		scope	ref	level	AQL
ASTM D3577-98	6 7 8 9	265 265 265 265	70 – 82 83 -- 95 96 -- 108 108 -- 120	0.10 0.10 0.10 0.10		24	18	750%	560%	holes: follow ASTM D5151; free of talc	dimension physical holes	ISO 2859	S-2 S-2 I	4.0 4.0 1.5
ISO ISO10282-94	6 7 8 9	260 270 270 280	72 – 83 84 – 94 96 – 108 108 -- 120	0.10 0.10 0.10 0.10	0.13 0.13 0.13 0.13	23	17	700%	560%	must be sterilized	dimension physical holes	ISO 2859	S-2 S-2 G-1	4.0 4.0 1.5
European EN455-2-95	6 7 8 9	260 270 270 280	72 – 83 84 – 94 96 – 108 108 -- 120			before aging 10.5 newtons after aging 7.5 newtons				holes: follow EN455-1-95	all	ISO 2859	S-2	4
Japanese JIS T9107-92	6 7 8 9	255 255 265 265	72 – 83 84 – 94 96 – 108 108 -- 120	class 1 finish P smooth: 0.10 finish T rough: 0.13 class 2 finish P smooth: 0.17 finish T rough: 0.13 smooth: 0.10		material N: 23 material S: 17	material N: 17 material S: 12	material N: 700% material S 550%	material N: 560% material S 490%	must be sterilized; sizes are color coded (ref. 1); conductivity test (ref. 2)	dimension physical holes	JIS Z 9015	S-2 S-2 S-4	4.0 4.0 1.5

latex surgical glove standards ltx srg glv st

GLOVE STANDARDS:

ANSI/ADA76-91	Non-sterile latex gloves for dentistry.
ADA Spec No. 102	Non-sterile nitrile gloves for dentistry.
ASTM D3577-91	Standard specification for rubber surgical gloves.
ASTM D3578-95	Standard specification for rubber examination gloves.
ASTM D5250-92	Standard specification for poly(vinyl chloride) gloves for medical application.
ASTM draft	Standard specification for nitrile examination gloves for medical application.
ISO10282-94	Single-use surgical rubber gloves-Specification.
ISO11193-94	Single-use rubber examination gloves-Specification.
AS/NZS 4011:1997	Single-use examination gloves—specification.
EN 455-1:1995	Medical gloves for single use. Part 1. Specification for freedom from holes.
EN 455-2:1995	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.
MS1155-89	Malaysian standard for rubber examination glove.
JIS T 9107-92	Japanese Industrial Standard. Surgical gloves.

ADA:	American Dental Association
ASTM:	American Society for Testing and Materials
CAN:	National Standard of Canada
EN:	European Standard
ISO:	International Standard

Other sizes are also available in many standards. Only common sizes are considered here.
Length is the over-all length and is the minimum requirement.
Width is the palm width and is always required with tolerances.
Physical requirements are expressed in tensile strength in megapascals and in ultimate % elongation at break.
These are minimum requirements. European standards require minimum force at break expressed in newtons.

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.
ASTM D5151	Test method for detection of holes in medical gloves.
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.

Applicable glove standards legends //stds legends