ARDL Physical and Chemical Glove Testing

ARDL Glove Testing - Physical and Chemical Testing Specifications and Methodologies

Your medical, surgical, examination, protective and single use gloves may need to be tested for safety in chemical rich environments. ARDL can perform in-depth analysis against a wide variety of chemical reagents used in hospital settings, military and aerospace applications and household chemicals.

BS EN 374-2 - Determination of Resistance to Water Penetration:
This is the reference test specified by the European Standard for the assessment of glove quality. Gloves must pass this test in order to prove that they are an effective barrier against liquids and micro-organisms. A statistical sample taken from a batch of gloves is subject to checks for pinholes and leaks by either inflation with air or by filling with water. Performance levels are assessed according to the acceptable quality levels (AQL) of the gloves. Gloves must meet at least level 2 of EN374-2 to be considered micro-organism resistant.

BS EN 374-3 - Determination of Resistance to Permeation by Chemicals
Resistance to permeation is assessed by measuring the time for a chemical to breakthrough the glove material. Samples, cut from the palms of gloves, are placed in a permeation cell which enables the chemical to be placed in contact with the outer surface of the gloves. Collection air or water is passed through the cell to collect any chemical that has broken through to the inside surface of the glove sample. ARDL's Chemical, Pharmaceutical & Microbiological Services laboratory is equipped with a FTIR spectrometer (to detect solvents), conductivity/pH electrodes (to detect acids, alkalis and salts) and UV/Visible spectrophotometer (to detect high boiling point, water soluble chemicals and solvents).

To carry the chemical pictogram, products must now meet at least level 2 of EN 374-2 as well as a performance level 2 when tested against three of the following chemicals: Acetone, Acetonitrile, Carbon Disulphide, Diethylamine, Ethyl Acetate, Methanol, n-Heptane, Sodium Hydroxide, Sulphuric Acid (96%), Tetrahydrofuran, Toluene.

Medical Gloves for single use:

- **BS EN 455-1:200 - Medical Gloves for Single Use - Part 1: Requirements and Testing for Freedom From Holes**

Specifies the requirments and gives test methods for physical properties of single use medical gloves (i.e. surgical gloves and examination/procedure golves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user. This method measures the strength thru force at break, using die cut samples from the intended gloves and in some cases after service life aging.

- **BS EN 455-2:2009 +A2:2013 - Medical Gloves for Single Use - Part 2: Requirements and Testing for Physical Properties**

This European Standard specifies requirements and gives test methods for physical properties of single use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user. This standard does not specify the size of a lot however. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots.

- **BS EN 455-3 - Part 3: Requirements and Testing for Biological Evaluation Section 5.1 - Endotoxins**

Monitoring method for the the endotoxin contamination of sterile gloves if the gloves are labelled with 'low endotoxin content'. This test method is performed for analytical determination of leachable proteins, powders and endotoxins using the Lowry Method or suitably validated method which has been verified against the Lowry Method.

- **ARDL 2140 - Lubricant Testing On Gloves**

This test method covers the ARDL proprietary procedure for the testing of different lubricants in reference to medical gloves.

ASTM Glove Testing Standards

- **ASTM D6319 – Standard Specification for Nitrile Examination Gloves for Medical Application**
- **ASTM D7558 – Standard Test Method for Colorimetric/Spectrophotometric Procedure to Quantify Extractable Chemical Dialkyldithiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators in Natural Rubber Latex and Nitrile Gloves**
- **ASTM D3577 - Standard Specification for Rubber Surgical Gloves (US Pharmacopeia)**
- **ASTM D3578 -Standard Specification for Rubber Examination Gloves**
- **ASTM D5151 - Standard Test Method for Detection of Holes in Medical Gloves**
- **ASTM D5250 - Standard Specification for Poly(vinyl chloride) Gloves for Medical Application**
- **ASTM D6124 - Standard Test Method for Residual Powder on Medical Gloves**
- **ASTM D6978 - Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs**
- **ASTM D7329 - Standard Specification for Food Preparation and Food Handling (Food Service) Gloves**
- **ASTM D7246 - Standard Test Method for Detection of Holes in Polyethylene Food Service Gloves**
- **ASTM D7161 - Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions**
- **ASTM D7160 - Standard Practice for Determination of Expiration Dating for Medical Gloves**
- **ASTM D6977 - Standard Specification for Polychloroprene Examination Gloves for Medical Application**

List of Glove Testing Specifications Performed by ARDL

ASTM D3577	ASTM D6977	ASTM D7558
ASTM D3578	ASTM D6978	BS EN 455-1, -2
ASTM D5151	ASTM D7160	BS EN 455-3
ASTM D5250	ASTM D7161	BS EN 374-2
ASTM D6124	ASTM D7246	BS EN 374-3
ASTM D6319	ASTM D7329	

FDA Detention/FDA Compliance Services

As an importer of latex/rubber medical devices, sooner or later you will be likely to experience US FDA Detention at Port of Entry. When this occurs ARDL can help you.

ARDL Provides:

- On-Site Sampling by ARDL Personnel
- Training of Third Party Personnel to Sample
- FedEx of Test Data to FDA Compliance Officer
- Telephone & Fax Contact with FDA at Port of Entry to Resolve Problems
- Familiarity with Special Requirements of Specific FDA Branch Offices

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