

GUIDE TO ISOLATION GOWN GUIDELINES

To select the appropriate Isolation gown, it's helpful to understand the standards and testing requirements for AAMI-rated gowns.

AAMI

ANSI/AAMI PB70:2012 provides standards for **liquid barrier performance**, with ratings for different levels of gown protection.¹ The AAMI Liquid Barrier standard addresses fluid protection in the areas most likely to come in direct contact with potentially infectious material.

Because the AAMI standard requires that **isolation gowns** be fully covered in the back, open-back gowns do not meet the AAMI standard, and cannot carry an AAMI rating. Both the fabric and all seams and attachments must meet AAMI standards. In addition, all AAMI Levels must meet a 4% AQL (Acceptable Quality Limit).

AAMI LEVEL 3

MODERATE FLUID BARRIER PROTECTION Use for the widest range of applications. Where moderate fluid protection is indicated.

Spray Impact Penetration $\geq 1.0g$
Hydrostatic Pressure $\geq 50cm$

AAMI LEVEL 2

MINIMAL TO LOW FLUID BARRIER PROTECTION For use when fluid exposure is expected to be low.

Spray Impact Penetration $\leq 1.0g$
Hydrostatic Pressure $\geq 20cm$

AAMI LEVEL 1

NO FLUID BARRIER PROTECTION Spray impact penetration $\leq 1.5g$

FOR DETAILED GUIDELINES,
GO TO www.aami.org

FDA

CLASS 1 CLEARED MEDICAL DEVICES

As a medical device company, we are regulated by the US Food and Drug Administration (FDA). The manufacturing sites for HALYARD* AAMI2 Gowns are registered with the FDA, and the FDA reviews and audits our manufacturing and quality systems to ensure we maintain FDA regulatory standards.

The FDA categorizes medical devices into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide assurance of safety and effectiveness.² Isolation gowns are classified as Class 1 Medical Devices.

FOR MORE GO TO www.FDA.gov



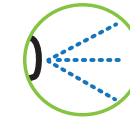
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GOWN TESTING

To make sure HALYARD* isolation gowns meet the standards set out by these organizations, they undergo a variety of standard tests, including:



FLUID AND BACTERIOPHAGE BARRIER (ASTM 1671) Measures resistance of materials used in protective clothing to bloodborne pathogens using viral penetration at 2psi and ambient pressure



IMPACT PENETRATION TEST (AATCC 42) Measures resistance of fabrics to penetration of water by spray impact, as measured by weight gain of a blotter in grams.



RESISTANCE TO BLOOD PENETRATION (ASTM F1670) Evaluates the resistance of a material to blood strikethrough, using synthetic blood with a surface tension and viscosity representative of blood and some body fluids.



HYDROSTATIC PRESSURE TEST (AATCC 127) Tests for fluid resistance by measuring the force required for water to penetrate gown fabric and seams.

1. Association for the Advancement of Medical Instrumentation (AAMI), Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (ANSI/AAMI PB70:2012), May 2012, pp 6-7 (§4.2.1-4.2.3)
https://www.aami.org/docs/default-source/products_store/standards/pb70_1206.pdf?sfvrsn=9d7b9544_2

2. U.S. Food and Drug Administration (FDA), Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings, Guidance for Industry and Food and Drug Administration Staff, Doc. #1500025, pp 1-9
<https://search.usa.gov/search?query=1500025&affiliate=fda1>