



Conti Group, LLC.

ISOLATION GOWN

BLUE

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PRODUCT SPECS	
Location	Mexico
Standards	¹ FDA Emergency Use Authorization
ANSI/AAMI PB70 Equivalent	² Level 4
ASTM F1670	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
ASTM 1671	Test System Phi-X174 Bacteriophage Penetration
16 CFR Part 1610	Standard for the flammability of clothing textiles
Material	Polypropylene
Description	Long Sleeve
	Adjustable cuff
	Sleeve and chest reinforcement
	Impervious to penetration of fluids
	Disposable
	Elastic Wrist
	Round Neck
	Non-sterile

PRODUCT PICTURE



MANUFACTUER SPECS

BATA DESECHABLE



Bata de trabajo para el odontólogo y personal auxiliar. Solapada a la espalda, garantiza una mayor protección del profesional. Los puños son de poliéster elásticos.

INDICACIONES: Ofrecer protección tanto al paciente como al personal sanitario, impidiendo el paso de microorganismos, fluidos corporales y partículas infecciosas en los procedimientos quirúrgicos.

MATERIAL: Repelente al agua formada por fibras de 90% polipropileno

Peso: 25 gms.

Puños poliéster: 115 gms.

Sistema de cierre: Solapada

Cuenta con un cierre a la cintura por dos cintas de ajuste

MARCA:  **DISPOSABLES**

Material desechable. la bata debe desecharse después de cada paciente y ante cualquier rotura o perforación durante el uso.

Insolation Gowns

Bata desechable con puño

27-0116 Bata con puño



Translation:

Disposable Gown

Isolation Gown for the dentist and auxiliary personnel. Overlapping behind, ensures greater protection from the professional. The cuffs are made of polyester elastics.

INDICATIONS: Provide protection to both patients and healthcare personnel, preventing the passage of microorganisms, body fluids and infectious particles in procedures.

MATERIAL: Water repellent made of 90% polypropylene fibers

Weight: 25 gms.

Polyester cuff: 115 gms.

Closure system: Overlapping

It has a closure at the waist by two adjustment straps

BRAND: DISPOSABLES

Disposable material. The gown should be discarded after each patient and before breakage or perforation during use.

Isolation Gowns

Disposable gown with cuff

27-0116 Gown with cuff

FDA Emergency Use Authorization (EUA)

¹FDA Emergency Use Authorization

Exempt from premarket notification requirements under section 510(k) of the FD&C Act.

FDA does not intend to object to the distribution and use of ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns that do not comply with the following regulatory requirements, where such surgical gowns do not create an undue risk in light of the public health emergency: Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81

FDA recognizes that when alternatives, such as FDA-cleared gowns, other surgical apparel, and/or gloves, are unavailable, individuals, including healthcare professionals, might improvise personal protective equipment (PPE). FDA does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared gowns, other surgical apparel, and/or gloves, are available.

FDA is taking steps to help expand the availability of gowns and other apparel and believes the policy set forth in this guidance may help address the urgent public health concerns caused by shortages of such products by taking a risk-based approach and clarifying the policies that FDA intends to apply to gowns and other apparel, including these products' associated indications and claims.

Information available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings>

²ANSI/AAMI PB70 Equivalentents

Level ¹	Test	Liquid Challenge	Result	Expected Barrier Effectiveness
1	AATCC 42 Impact Penetration ²	Water	= 4.5 g	Minimal water resistance (some resistance to water spray)
2	AATCC 42 Impact Penetration	Water	= 1.0 g	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
3	AATCC 127 Hydrostatic Pressure ³	Water	= 20 cm	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
4	AATCC 42 Impact Penetration	Water	= 1.0 g	Blood and viral penetration resistance (2 psi)
	AATCC 127 Hydrostatic Pressure	Water	= 50 cm	
4	ASTM F1670 Synthetic Blood Penetration Test (for surgical drapes)	Surrogate Blood	no penetration at 2 psi(13.8 kPa)	Blood and viral penetration resistance (2 psi)
	ASTM F1671 Viral Penetration Test (for surgical and isolation gowns)	Bacteriophage Phi-X174	no penetration at 2 psi(13.8 kPa)	

¹ In order of increasing protection

² American Association of Textile Chemists and Colorists (AATCC) 42 Water resistance: impact penetration test determines the ability of a material to resist water penetration under spray impact [AATCC 2000]

³ AATCC 127 Water resistance: hydrostatic pressure test determines the ability of a material to resist water penetration under constant contact with increasing pressure [AATCC 1998]

