

# EHSP-800

## AAMI LEVEL-1 ISOLATION GOWN



<b>Product Name:</b>	AAMI Level-I Isolation Gown
<b>Product Description:</b>	Minimal Risk, Used for Basic Care, Protective Procedure Gown, Standard Isolation, Cover Gown for Visitors or used for Standard Procedure Medical Units, AAMI Level 1
<b>Manufacturer:</b>	ECEP HAN
<b>Product SKU:</b>	L1/B35GSM-GWN-2020
<b>Brand Name:</b>	EHSP
<b>Product Model:</b>	EHSP 800
<b>Product Color:</b>	Blue
<b>Private label</b>	Yes Possible, Shall be coordinated with ECEP HAN
<b>Goods in Stock?</b>	Yes
<b>Sizes Available</b>	S, M, L, XL, 2XL, 3XL
<b>Cuff Style</b>	3" Ribbon Elasticated
<b>Fastening Type</b>	Adjustable Velcro Neck, Waist Ties
<b>Height</b>	42" Tall
<b>Gender</b>	Unisex
<b>Product Material</b>	PP+PE (35 GSM)
<b>Sterility</b>	Non-sterile
<b>Usage</b>	Disposable
<b>User</b>	Adult
<b>Other Features</b>	Overlock Sewn, Full Coverage with overlapping, neck part comes with overlapping cloth, back neck tie comes with 2" and 4" adjustable Velcro and has 1" extended overlapping tips for easy gripping.







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Rev 02

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Attn: Nick Hammond

ECEP HAN NORTH AMERICA LLC  
8260 E. Gelding Dr. Suite 101  
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ARIZONA, USA

Revised Certificate

**AAMI PB70 Liquid Barrier Performance and Classification**

Test Article: EHSP 800 – Isolation Gown Level 1

A total of thirty-two (32) specimens were tested from thirty-two (32) test articles. Specimens were chosen from the critical zones as described in AAMI PB70 for an isolation gown. Test specimens were subjected to the following test:

**AATCC 42 Water Resistance: Impact Penetration Test**

Based on the results of the testing as summarized in the attached report number 2005333, the product listed above was classified as **AAMI PB70 Level 1**.

Revision Statement: This certificate was revised to correct the Istanbul address and to add the USA address. The test results were not affected.

**Record Storage:** All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by  Date 



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ATTN: Nick Hammond

Lab # 2005333  
PO # NA

Test Article: EHSP 800 - Isoaltion Gowns Level 1  
Part # NA Lot # NA Batch # NA

### AATCC 42 Water Resistance: Impact Penetration Test

Test article received: 7/14/2020  
Test start date: 7/15/2020  
Test termination date: 7/16/2020  
SOP No. (current version): LEXLP-074

**Procedure:** Thirty-two (32) sections each measuring 178 x 330 mm were cut from 32 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens and one (1) blotter sheet for each were preconditioned at  $65 \pm 2\%$  rh and  $21 \pm 1^\circ\text{C}$  for a minimum of 4 hours. Test samples were then clamped to the incline stand of an Impact Tester. Blotter paper was weighed and inserted beneath the test sample. Deionized Water (DIW) heated to  $27 \pm 1^\circ\text{C}$  was poured into the funnel and the water sprayed onto the test article. The blotter paper was removed and re-weighed.

The post-weight for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

Post -Weight Gain Acceptance Criteria		
Level 1	Level 2	Level 3
$\leq 4.5 \text{ gm}$	$\leq 1.0 \text{ gm}$	$\leq 1.0 \text{ gm}$

**Results:** A total of 32 / 32 specimens had a weight gain of  $\leq 4.5 \text{ gm}$ .

**Conclusion:** Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 1.

**Record Storage:** All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by Beecham Duhur Tech: AP Date 7-20-20



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