

# EHSP-820/3

## AAMI LEVEL-3 ISOLATION GOWN



**EHSP**  
Innovation.Speed.Accuracy  
*for Your Protection*



<b>Product Name:</b>	AAMI Level-III Isolation Gown
<b>Product Description:</b>	Moderate risk, Used for arterial blood draw, inserting an intravenous (IV) line, in emergency rooms and Trauma cases AAMI Level 3
<b>Manufacturer:</b>	ECEP HAN
<b>Product SKU:</b>	L3/W55GSM-GWN-2020
<b>Product Description:</b>	Low Risk, Used for blood draw, suturing, in Intensive Care (ICU), or Pathology Laboratory, AAMI Level 3
<b>Manufacturer:</b>	ECEP HAN
<b>Product SKU:</b>	L3/B40GSM-GWN-2020
<b>Brand Name:</b>	EHSP
<b>Product Model:</b>	EHSP 810
<b>Product Color:</b>	White
<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 (40 GSM)
<b>Sterility</b>	Non-sterile

**Ecep Han**  
Trading for good.

ECEP HAN MEDİKAL TEKSTİL SAN VE TİC.LTD.ŞTİ.

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Rev 01

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Attn: Nick Hammond

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ARIZONA, USA

Revised Certificate  
**AAMI PB70 Liquid Barrier Performance and Classification**

Test Article: EHSP 820-3 Gown

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 tests:

**AATCC 42 Water Resistance: Impact Penetration Test**  
**AATCC 127 Water Resistance: Hydrostatic Pressure Test.**

Based on the results of the testing as summarized in the attached reports, numbers 2004657 and 2004658, the product listed above was classified as **AAMI PB70 Level 3**.

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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Akcaburgaz Mah. Akcaburgaz CD. NO:20 Suite 28  
Veis Merkezi, Esenyurt, Turkey,  
ATTN: Nick Hammond

Lab # 2004658  
PO # 100

Test Article: EHSP 820-3 Gown  
Part # NA Lot # NA Batch # NA

### AATCC 127 Water Resistance: Hydrostatic Pressure Test

Test article received: 6/19/2020  
Test start date: 6/22/2020  
Test termination date: 6/22/2020

**Procedure:** Thirty-two (32) sections each measuring 200 mm x 200 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 were preconditioned at  $65 \pm 2\%$  rh and  $21 \pm 1^\circ\text{C}$  for a minimum of 4 hours. Individual specimens were clamped into the Hydrostatic Tester and analyzed.

The hydrostatic pressure required for water penetration for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

Hydrostatic Pressure Acceptance Criteria	
Level 2	Level 3
$\geq 20 \text{ cmH}_2\text{O}$	$\geq 50 \text{ cmH}_2\text{O}$

**Results:** A total of 32 / 32 specimens had a hydrostatic pressure for water penetration of  $\geq 50 \text{ cmH}_2\text{O}$ .

**Conclusion:** Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

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

Approved by 

Tech: AP/GP Date 6-26-20



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Ve Is Merkezi, Esenyurt, Turkey,  
ATTN: Nick Hammond

Lab # 2004657  
PO # 100

Test Article: EHSP 820-3 Gown  
Part # NA Lot # NA Batch # NA

### AATCC 42 Water Resistance: Impact Penetration Test

Test article received: 6/19/2020  
Test start date: 6/22/2020  
Test termination date: 6/23/2020  
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
$\leq 4.5$ gm	$\leq 1.0$ gm	$\leq 1.0$ gm

**Results:** A total of 32 / 32 specimens had a weight gain of  $\leq 1.0$  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 3.

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

Approved by  Tech: AP/GP Date 6-26-20



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