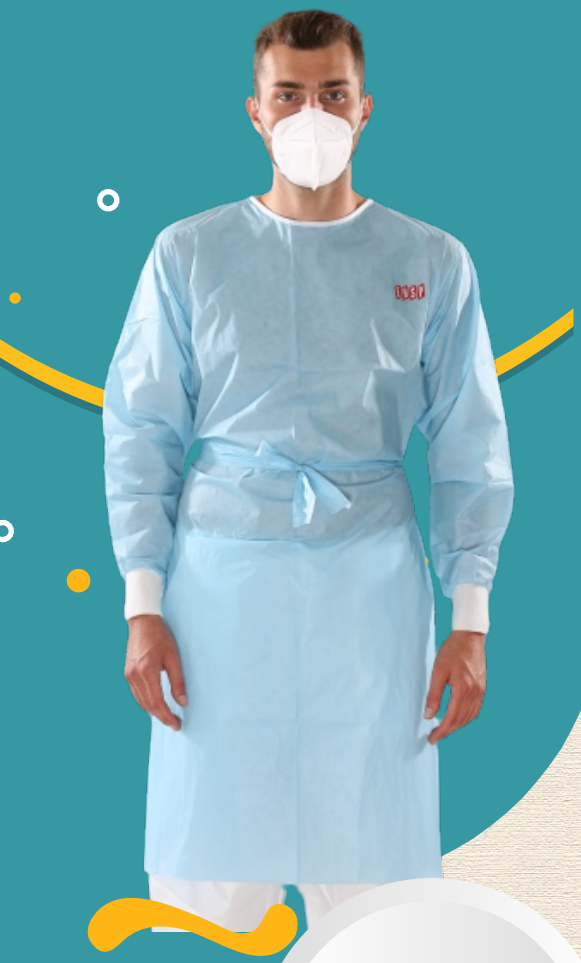
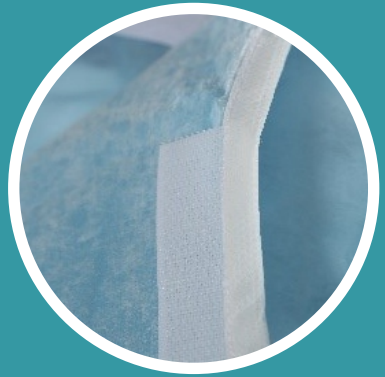
EHSP-810
AAMI LEVEL-2 ISOLATION GOWN



Product Name:	AAMI Level-II Isolation Gown
Product Description:	Low Risk, Used for blood draw, suturing, in Intensive Care (ICU), or Pathology Laboratory, AAMI Level 2
Manufacturer:	ECEP HAN
Product SKU:	L2/B40GSM-GWN-2020
Brand Name:	EHSP
Product Model:	EHSP 810
Product Color:	Blue
Private label	Yes Possible, available up on request with ECEP HAN
Goods in Stock?	Yes
Sizes Available	S, M, L, XL, 2XL, 3XL
Cuff Style	3” Ribbon Elasticated
Fastening Type	Adjustable Velcro Neck, Waist Ties
Height	42” Tall
Gender	Unisex
Product Material	PP+PE (40 GSM)
Sterility	Non-sterile
Usage	Disposable
User	Adult
Other Features	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.

EHSP
Innovation.Speed.Accuracy
For Your Protection



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Trading for good..

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Rev 01

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Attn: Nick Hammond

ECEP HAN NORTH AMERICA LLC
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ARIZONA, USA

Revised Certificate

AAMI PB70 Liquid Barrier Performance and Classification

Test Article: EHSP 810 – Isolation Gown Level 2

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 a surgical 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 2005355 and 2005356, the product listed above was classified as **AAMI PB70 Level 2.**

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 9-25-20

ANAB ACCREDITED TESTING LABORATORY

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ATTN: Nick Hammond

Lab # 2005356
PO # NA

Test Article: EHSP810 - Isolation Gowns Level 2
Part # NA Lot # NA Batch # NA

AATCC 127 Water Resistance: Hydrostatic Pressure Test

Test article received: 7/14/2020
Test start date: 7/16/2020
Test termination date: 7/17/2020

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±2% rh and 21±1ºC 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
≥ 20 cmH_2O	≥ 50 cmH_2O

Results: A total of 32 / 32 specimens had a hydrostatic pressure for water penetration of ≥ 20 cmH_2O.

Conclusion: Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 2.

The gowns used for this study were preconditioned at 21 ± 1°C and 65 ± 2% rH for 17 hours 40 minutes (min 4 hours required). For approximately 7 hours and 15 minutes during that time the humidity was above spec by 1-6.5%. This additional time at increased moisture did not impact the test as all specimens met the requirements for an AAMI PB70 Level 2 gown. This excursion was documented in IRR #20-047.

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: GP Date 7/21/20

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ATTN: Nick Hammond

Lab # 2005355
PO # NA

Test Article: EHSP810 - Isolation Gowns Level 2
Part # NA Lot # NA Batch # NA

AATCC 42 Water Resistance: Impact Penetration Test

Test article received: 7/14/2020
Test start date: 7/16/2020
Test termination date: 7/17/2020
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±2% rh and 21±1°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± 1°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
≤ 4.5 gm	≤ 1.0 gm	≤ 1.0 gm

Results: A total of 32 / 32 specimens had a weight gain of ≤ 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 2.

The gowns used for this study were preconditioned at 21 ± 1°C and 65 ± 2% rH for 17 hours 40 minutes (min 4 hours required). For approximately 7 hours and 15 minutes during that time the humidity was above spec by 1-6.5%. This additional time at increased moisture did not impact the test as all specimens met the requirements for an AAMI PB70 Level 2 gown. This excursion was documented in IRR #20-047.

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: GP/AP Date 7/21/20

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

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