

LEVEL 4 – CPE DISPOSABLE ISOLATION GOWNS

- AAMI Level 4 Gown
- Back : Open Back Tie
- Closure: On
- Color: Blue (may vary)
- Composition/Ingredients: Chlorinated Polyethylene
- Disposable: Yes
- Fluid Resistant: Yes
- Item Type Latex: Latex Free
- Shipping: 150pcs/carton
- Size: Standard
- Weight: 53g
- Certification: CE, FDA
- Description: CPE Gown is made from lightweight breathable and comfortable odorless chlorinated polyethylene. It has no stimulus to skin and is a high structure strength with excellent tensile, tear and abrasion resistance to provide reliable barriers to water steam or blood and other fluids.

Proof of Life and Water Test Videos (Our Factory):

<https://drive.google.com/drive/folders/1dpfbd6OrgtvI9y1NQaJR3QFbRp1upaaF?usp=sharing>

Detailed Test Report: <https://drive.google.com/file/d/1h20IR3quPPVjfHHvoQcMqd7ITY0sK-WM/view?usp=sharing>



Please note: Colors May Vary depending on availability and are available in Blue and Yellow



Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Name: [REDACTED] MEDICAL TECHNOLOGY CO., LTD.

Add: Economic Development Zone, Qihe County, Dezhou, Shandong, China

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

The Owner/ Operator Number for this Registration is : [REDACTED]

Listing No	Code	Device Name
D375314	GEA	Isolation Gown, Protective Clothing
D375316	BYG	Medical Face Shield
D375313	HOY	Medical Safety Goggles
D375312	IEA	Disposable Medical Surgical Mask

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate holder's device or establishment by the U.S Food and Drug Administration.

ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Mar. 17, 2020

Date of expiration: Dec. 31, 2020

SH OFFICE
TEL: [REDACTED]
[REDACTED]
[REDACTED] (Highly, CO USA 0001)
[REDACTED]



CERTIFICATE

Of Directive 2011/65/EU and Amending Directive (EU)2015/863
conformity

Registration No.: TS [REDACTED]

Applicant : Shandong Housewares Manufacturing Co.,Ltd
Address : [REDACTED] Jia Xiang County ,Jining ,
Shandong
Product : DISPOSABLE CPE GOWNS (NON-MEDICAL)
Material : 25GMS, 50G/PC
Reference Model No. : /

The submitted products have been tested by us with the listed standards and found in compliance with the following standards:

IEC 62321-4:2013, IEC 62321-5:2013, IEC 62321-6:2015, IEC 62321-7-2: 2017, IEC 62321-8:2017—
Procedures for Determination of Levels of Regulated Substances in Electrical Products

The test result derived from report TS2020040912 and the test results of the submitted products have been accorded with the following standards: 2011/65/EU and Amending Directive (EU)2015/863. The tests were performed in normal operation mode. The test results apply only to the particular sample tested and to the specific tests carried out. This certificate applies specifically to the sample investigated in our test reference number only.

Other relevant directives have to be observed.



Certified By Meng Wei
Manager



Product Technology Service (Ningbo) Co., Ltd.
5-7F, 59#, Huayu Road, Yinzhou District, Ningbo, 315192 P.R China

Website: <http://www.pts-lab.com/> Email: info@pts-lab.com