

## LEVEL 2 – SBPP DISPOSABLE ISOLATION GOWNS

- Ethylene Oxide Sterilization
- AAMI Level 2
- Fabric: Non-Woven Fabric
- Type: Disposable Isolation Gown
- Shipping: 150pcs/Carton
- Size: Standard
- Weight: 35g
- Cuffs: Knitting & Elastic
- Certification: CE, FDA
- Description: Soft & Comfortable, Easy to Wear, Light Weight and breathable, Disposable and Economic. This high quality surgical gown is sterilized provide reliable and selective blood or any other liquid. This specially designed gown can allow doctors or nurses feel comfortable with long term use.

Video Proof of Life & Water Test at Factory:

[https://drive.google.com/drive/folders/1e4FdqusSIANTWIRG54DlxWnhLCM\\_EDJt?usp=sharing](https://drive.google.com/drive/folders/1e4FdqusSIANTWIRG54DlxWnhLCM_EDJt?usp=sharing)

Photos:



*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	CEA	Isolation Gown, Protective Clothing
D375316	BYG	Medical Face Shield.
D375313	HOY	Medical Safety Goggles
D375312	KEA	Disposable Medical Surgical Mask

ABimed 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. ABimed 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.

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

Date of verification: Mar. 17, 2020

Date of expiration: Dec. 31, 2020

SI OFFICE

TEL: [REDACTED]

[REDACTED]

[REDACTED] Bldg 100, CO USA 80601

[REDACTED]

[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

Apr 14 2020



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