XINLE HUABAO MEDICAL PRODUCTS CO.,LTD

XINLE HUABAO www.huabaoyiyong.com

CE **Product Name：** Isolation Gowns

Specification

【 Main Properties of Product 】

◉ The product is made of non-woven, PE laminated non-woven with a full range of specifications, S/M/L/XL/XXL. It is effective against dirt, moisure and fluid.

【 Application 】

◉ This product is mainly used for health protection in the medical institution.

【Caution】

◉ The product should be stored in suitable temperature, good ventilation ,clean and no corrosive gas indoor.

◉ The product is valid for three years. Please use within period of validity.

◉ Do not use if package is damaged.

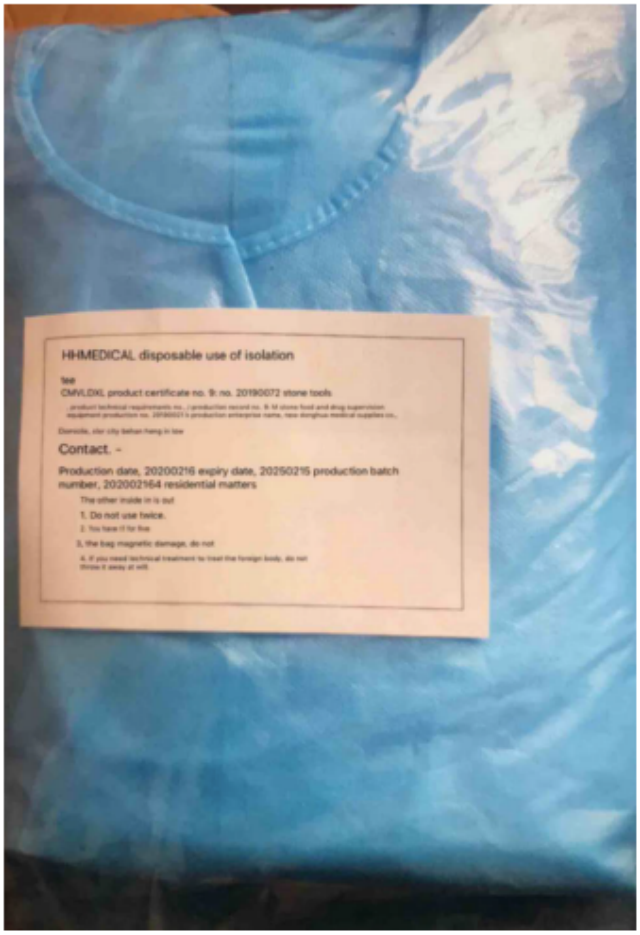
◉ The product is for single use only.After use,please dispose according to local relevant laws and regulations.

NO.	Symbol	Mean
1		CAUTION
2		DO NOT USE IF PACKAGE IS DAMAGED
3		DO NOT REUSE
4		KEEP AWAY FROM SUNLIGHT
5		MANUFACTURER
6	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
7		KEEP DRY
8		USE BY
9	LOT	BATCH CODE
10		DATE OF MANUFACTURE

XINLE HUABAO MEDICAL PRODUCTS CO.,LTD
Dongguan,Cheng'an Town,Xinle City, Hebei Province,050701,P.R.China
Web:http//www.huabaoyiyong.com
E-mail:yiyong@huabaosuliao.com
Phone:0086-311-88561291 88561292 88564183
Fax:0086-311-88562297

EC REP
Wellkang Ltd t/a Wellkang Tech Consulting
Suite B,29Harley Street
LONDON W1G 9QR, England, United Kingdom

NO.: Q/HBMP06.45 -2020 Version No: A/1 Date issued: 2020-03-02


HHMEDICAL disposable use of isolation
CMVLDXL product certificate no. 9: no. 20190072 stone tools
Contact. -
Production date, 20200216 expiry date, 20250215 production batch number, 202002164 residential matters
The other inside in is out
1. Do not use twice.
3. the bag magnetic damage, do not

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CE Technical Documentation Review Report

Applicant:	**XINLE HUABAO MEDICAL PRODUCTS CO.,LTD** Dongguan, Cheng'an Town, Xinle City, Hebei Province,050701,China
Report Number:	**16806072.001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	Please see attachment
Type(s)/Model(s):	Please see attachment
Classification:	Class I (according to manufacturer's declaration)
Examination period:	Aug.18.2016
Date of expiry:	Aug.17.2021
Review result:	During the examination of the provided Technical Documentation (No.: Q/HBMP06.36-2015, Revision: A/1, dated 2015-04-20), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd

Yuhong CHEN
Manager
Medical Services

Safety • Quality Assurance TÜV Rheinland Approved

Rev.01, 2002-10-10

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CE Technical Documentation Review Report

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Attachment to

Report Number: **16806072.001**

Applicant: **XINLE HUABAO MEDICAL PRODUCTS CO.,LTD**
Dongguan, Cheng'an Town, Xinle City, Hebei Province, 050701,China

Product(s):

non-sterile non-woven products
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Face Masks, Examination Sheets, Shoe Covers)

non-sterile non-woven and PE composited products
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile PE products
(Surgical Gowns, Surgical Drapes, PE Gowns, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile paper products
(Dental Bibs, Bed Sheets, Examination Sheets)

non-sterile PE and paper composited products
(Dental Bibs, Bed Sheets, Examination Sheets)

Type(s)/Model(s): Please see above

Examination period: Aug.18.2016

Date of expiry: Aug.17.2021

TÜV Rheinland (China) Ltd.

Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

Product Safety • Quality Assurance TÜV Rheinland Approved

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Test Report No.: 721616476-1
Report Date: 4 September 2014

ORIGINAL

SUBJECT	**Resistance To Wet Microbial Penetration Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD PSB Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Xinle Huabao Medical Products Co., Ltd.**
CLIENT ADDRESS	Cheng'an Industrial Park, Xinle City, Hebei Province, China 050701
TEST PERIOD	25-Aug-2014~29-Aug-2014

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

TÜV SÜD PSB Products Testing (Shanghai) Co., Ltd.

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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Regional Head Office:
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No.88 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

Resistance To Wet Microbial Penetration Test

1. Purpose

For evaluation of resistance to wet bacterial penetration.

2. Sample description was given by the client

PE COATED WITH NONWOVEN FABRIC TYPE: 55gsm (STERILE)

3. Reference

EN 13795:2011+A1:2013
EN ISO 22610:2006

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 29213
4.2 Peptone water
4.3 Nurient agar plates (14cm diameter)
4.4 Carrier material: PU film (30μm thickness)
4.5 Covering material: HDPE film
4.6 Cylindrical body
4.7 RULLA 2 Wet-Penetration-Test
4.8 Oven

5. Test specimen

5.1 Sample had been sterilized. Cut 5 test specimens 25cm×25cm under aseptic conditions.

6. Procedure

6.1 Preparation
  6.1.1 Six petri dishes, 14cm in diameter, were filled with nutrient agar to (3±0.2)mm from the brim.
  6.1.2 Preparation of donor: Evenly distribute 1.0mL of the *Staphylococcus aureus* suspension with a concentration of 1.5×10^4 CFU/mL over an area corresponding to the lid of the agar plate of the carrier. Dry the donor at 56°C for approximately 30min.
6.2 Place the first agar plate on the turntable.
6.3 Put a test specimen on the ring, and put the donor, contaminated side down, on the specimen. Cover the PU film with a piece of HDPE film, then push the outer ring down firmly so that the three materials were securely held between the two rings.
6.4 With the materials slightly slack, place the ring on the first lidless agar plate, such that the steel ring hangs freely outside the turntable. Apply the finger to the HDPE film just inside the brim in such a way that the test specimen comes into contact with the agar surface. Run the test as described for 15min with a finger pressure of 3N.
6.5 After 15min, remove the ring and the assemblage immediately and retain.
6.6 Remove the first agar plate from the turntable and seal it with its lid. Immediately put the second agar plate on the turntable, together with the retained ring assemblage.
6.7 Perform the above-mentioned procedure on the same test assemblage using the next four plates.

6.8 When five plates have been tested, remove and discard the donor, turn the test specimen upside down and cover it with the HDPE film.

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ORIGINAL

6.9 Run the sixth plate for 15min on the first replicate to complete the test run.
6.10 Repeat the procedure 6.2 to 6.9 for each of the other four test specimen, using a freshly prepared donor with each test specimen.
6.11 If liquid had accumulated on the agar surface, dry the plate(s) on a clean beach and incubate the six agar plates with their lids on for 48h at 35°C.
6.12 Count the colonies of *Staphylococcus aureus* on each plate. Disregard the count in the area with a radius of 15mm around the centre of the plate.

7. Calculation

7.1 The estimated bacterial challenge, T, was calculated as follows:
$T = Z+X_1+X_2+X_3+X_4+X_5$
Where
Z is the number of colonies from the top side of the test specimen that are left over after the five agar plates have been run, measure on the sixth agar plate (plate 6);
$X_1,\cdots,X_5$ are the numbers of colonies on the 5 plates in one replicate test, using the same test specimen and donor.

7.2 The cumulative penetration ratio of plates 1 to 5, $R_{CUM1},\cdots,R_{CUM5}$, was calculated as follows:

$$R_{CUM1}=\frac{X1}{T}$$

$$R_{CUM2}=\frac{(X1+X2)}{T}$$

$$R_{CUM3}=\frac{(X1+X2+X3)}{T}$$

$$R_{CUM4}=\frac{(X1+X2+X3+X4)}{T}$$

$$R_{CUM5}=\frac{(X1+X2+X3+X4+X5)}{T}$$

7.3 Barrier index, I_B, was calculated as follows:
$I_B=6-(R_{CUM1} +R_{CUM2} +R_{CUM3} +R_{CUM4} +R_{CUM5})$

8. Test results

Test Items*			Test Results					Test Methods
			1	2	3	4	5	
Resistance to Microbial Penetration-Wet	Test time \(CFU)	15 min	0	0	0	0	0	EN ISO 22610:2006
		30 min	0	0	0	0	0	
		45 min	0	0	0	0	0	
		60 min	0	0	0	0	0	
		75 min	0	0	0	0	0	
		Donor	6	7	10	73	266	
	Barrier Index, I_B	Individual	6.000	6.000	6.000	6.000	6.000	
		Mean	6.000					

Note1: Suspension Conc.:1.5×10^4 CFU/ml.

Note2:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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Test Report No.: 721616476-2
Report Date: 4 September 2014

ORIGINAL

SUBJECT	**Bursting Strength Test in Dry and Wet State**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD PSB Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Xinle Huabao Medical Products Co., Ltd.**
CLIENT ADDRESS	Cheng'an Industrial Park, Xinle City, Hebei Province, China 050701
TEST PERIOD	25-Aug-2014~29-Aug-2014

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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ORIGINAL

Bursting Strength Test in Dry and Wet State

1. Purpose

For evaluation of bursting strength in dry and wet state.

2. Sample description was given by the client

PE COATED WITH NONWOVEN FABRIC TYPE: 55gsm (STERILE)

3. Reference

EN 13795:2011+A1:2013
EN ISO 13938-1:1999
EN 29073-3:1992

4. Apparatus

Mullen Burst Tester: a test area of 8 cm^2 (32mm diameter), a constant rate of increase in volume of (95±5)cm^3/min.

5. Test specimen

5.1 Take test specimens from the critical area and non-critical area as requested by client.
5.2 Cut 10 critical area test specimens and 5 non critical area specimens which are at least 15cm×15cm.
5.3 Prior to testing the dry test specimens were conditioned at (20±2)℃ and (65±5)% relative humidity for at least 4 hours.
5.4 For wet test, soak the test specimens for 1h in a solution containing 1g of non-ionic wetting agent per liter of distilled water. Prior to testing the wet test specimens were not conditioned.

6. Procedure

6.1 For dry test
- 6.1.1 Ensure that the test machine was reset, with the diaphragm flat and the maximum pressure indicator was set to zero.
- 6.1.2 Place the test specimen face side up and over the diaphragm so that it lay in a flat tensionless condition, avoiding distortion in its own plane. Clamp it securely in the circular holder, avoiding jaw damage, to prevent slippage during the test. For sleeve seam, put the seam on the central line.
- 6.1.3 Apply pressure to the test specimen until the test specimen bursts. Immediately after burst, reverse the apparatus to starting position. Record the bursting pressure.
- 6.1.4 Examine the test specimen. If the test specimen bursts close to the edge of the clamping device or the test specimen slipped in the clamp then discard the results and repeat the test with another test position.
- 6.1.5 Repeat the procedure 6.1.1 to 6.1.4 for each of the other four test specimens.

6.2 For wet test
Remove a test sample from the water, placing it on blotting paper to remove excess water. Immediately perform the test according to 6.1.

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7. Calculation

Because the individual bursting pressure values of each specimen were not similar, the individual result of each specimen was used and the mean of the five bursting pressure values did not calculated.

8. Test results

Test Items*			Test Results	Test Methods
Bursting Strength (kPa)	Dry	1	137.9	EN ISO 13938-1:1999
		2	206.9	
		3	172.4	
		4	172.4	
		5	206.9	
	Wet	1	206.9	
		2	206.9	
		3	172.4	
		4	172.4	
		5	172.4	

Note1:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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Test Report No.: 721616476-3
Report Date: 4 September 2014

ORIGINAL

SUBJECT	**Cleanliness of Microbial Test**
TEST LOCATION	**TÜV SÜD China**
	TÜV SÜD PSB Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Xinle Huabao Medical Products Co., Ltd.**
CLIENT ADDRESS	Cheng'an Industrial Park, Xinle City, Hebei Province, China 050701
TEST PERIOD	25-Aug-2014~29-Aug-2014

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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ORIGINAL

Cleanliness of Microbial Test

1. Purpose

For determination of a population of microorganisms (Facultative, non-fastidious, aerobic bacteria; Yeasts and moulds).

2. Sample description was given by the client

PE COATED WITH NONWOVEN FABRIC TYPE: 55gsm (NON-STERILE)

3. Reference

EN 13795:2011+A1:2013
EN ISO 11737-1:2006

4. Apparatus and materials

4.1 Stomacher (BagMixer400)
4.2 Stomacher bag
4.3 Eluent: Buffered peptone water
4.4 Tryptone soya agar (TSA)
4.5 Sabouraud dextrose agar (SDA)
4.6 Filtration equipment
4.7 Sterilized membrane (0.45μm)

5. Test specimen

5.1 Take a total of 6 test specimens.(Each sample was taken 2 test specimen. One test specimen for Facultative, non-fastidious, aerobic bacteria and one test specimen for Yeasts and moulds.)
5.2 Cut a test specimen 100mm×100mm under aseptic condition.

6. Procedure

6.1 Bioburden test
- 6.1.1 Cut a test specimen into small pieces, and enclose in a stomacher bag under aseptic conditions.
- 6.1.2 Pour into 100mL eluent (buffered peptone water) and process 3min in a stomacher individually by highest speed. Filtrate the eluent by membrane filter.
- 6.1.3 Individually, membrane filters were put on TSA and incubated 5d at 35°C for Facultative, non-fastidious, aerobic bacteria, and on SDA 7d at 25°C for Yeasts and moulds.
- 6.1.4 Test 3 test specimens for Facultative, non-fastidious, aerobic bacteria. And test 3 test specimens for Yeasts and moulds.

6.2 Recovery efficiency test
- 6.2.1 Take one test specimen from Facultative, non-fastidious, aerobic bacteria and one test specimen from for Yeasts and moulds.
- 6.2.2 Repetitive treatment as bioburden test four times.
- 6.2.3 Finally, coating the surface of test specimens with molten medium (TSA and SDA), allowing the media to solidify and exposing the test specimens to specified culture conditions.

6.3 The colonies formed on incubation were counted.

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7. Calculation

Treatment	TSA	SDA
1	1	2
2	0	0
3	0	0
4	0	0
Agar overlay	0	0
Total colony count	1	2

7.1 Recovery efficiency (%)= $\frac{\text{Number recovered by first treatment}}{\text{Total number recovered}} \times 100$

7.2 Correction factor= $\frac{100}{\text{Recovery efficiency (\%)}}$

Items	B	F
Recovery efficiency (%)	100.0	100.0
Correction factor	1.0	1.0

Note: B= Facultative, non-fastidious, aerobic bacteria
F= Yeasts and moulds

7.3 Bioburden=Number recovered by first treatment × Correction Factor

8. Test results

Test Items*	Test Results			Test Methods
	Specimen 1	Specimen 2	Specimen 3	
Facultative, non-fastidious, aerobic bacteria (CFU/100cm^2)	1	3	<1	EN ISO 11737-1:2006 B.2.2.1/B.4.2
Yeasts and moulds (CFU/100cm^2)	2	1	4	

Note1:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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