TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60145760 0001

Report No.: 16806100 007

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

Products:
For the Following Medical Devices the Scope Covers only the Aspects of Manufacture Concerned with Securing and Maintaining Sterile Conditions

(See Attachment for Products included)

Replaces Approval, Registration No.: DD 60110792 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-01-19

Date: 2020-01-19

Notified Body
TÜV Rheinland LGA Products GmbH
Zertifizierstelle
Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

10/020 d 04.08 TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60145760 0001
Report No.: 16806100 007

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

Products:

- Sterile Non-woven Products (Surgical Gowns, Surgical Drapes, Isolation Gowns, Coveralls, Face Masks)
- Sterile Non-woven and PE Composited Products (Surgical Gowns, Surgical Drapes, Isolation Gowns, Coveralls)

Notified Body

Date: 2020-01-19

Jing Zhang

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LGA
Precisely Right.

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

XINLE HUABAO MEDICAL
PRODUCTS CO., LTD.
Dongguan, Cheng'an Town
050701 XINLE CITY, HEBEI PROVINCE
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date January 19, 2020

Application for : **QMS Produktion, Anhang V MDD**
Certificate No. : DD 60145760 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60145760 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

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Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

DICHIARAZIONE DI CONFORMITÀ

(ALLEGATO VII DIRETTIVA 93/42/CEE)

CE

Identificativo di registrazione Repertorio BD/RDM: 2027953

Fabbricante:

Xinle Huabao Medical Products Co., Ltd.

Dongguan, Cheng, an Town, Xinle City, Hebei Province, 050701, China

Mandatario Europeo:

Wellkang Ltd. Suite B, 29 Harley Street, London W1G 9QR, UK

Del prodotto:

Denominazione	**CAMICE MEDICO monouso**
Tipologia / Classe dispositivo	**Classe I - Non sterile**
Marca	**XINLE HUABAO MEDICAL PRODUCTS**
Categoria	**B [B004] S - M - L - XL - XXL**
Anno di Costruzione	**2020**
Lotto	

Il prodotto sopraindicato è conforme alle disposizioni delle seguenti direttive e successivi emendamenti:

93/42/CEE Direttiva Dispositivi Medici e modificata dalla Direttiva 2007/47/EC.

Dichiara inoltre che il prodotto è conforme ai seguenti standard:

EN 13795:2019 Camici monouso Classe I ad uso medico – Requisiti e metodi di prova.

Procedur a di valutazione della conformità: **Modulo A (CE Dichiarazione di conformità (allegato VII) + fascicoli tecnici)**

Roma, 28/10/2020

Firma

Fabbricante: 刘敏奇

新乐华宝医疗用品有限公司
XINLE HUABAO MEDICAL PRODUCTS CO., LTD
刘 敏 奇
LIU MIN QI

XINLE HUABAO PLASTIC PRODUCTS CO., LTD.
NO.210, NANHUAN ROAD, XINLE CITY, HEBEL PROVINCE

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A) The Disposable Isolation Gown is made from nonwoven and PE composited material, and consists of a front and back cut piece(including two sleeves, two collar bindings and two belts).The product is suitable for general isolation in out-patient, sickroom and inspection room of medical institution.
SGS Internal Ref No.	:	SL120012511014TX
Roll/ Lot No.	:	20200520DDR
Sample Receiving Date	:	Jun 04, 2020
Testing Period	:	Jun 04, 2020 – Jul 07, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed	:	Selected test(s) as requested by applicant

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SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center

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Member of the SGS Group (SGS SA)

Comment:

Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns(EN 13795-1:2019)	(A)
Clause 4 Bursting strength-Dry	M
Clause 4 Bursting strength-Wet	M
Clause 4 Tensile strength-Dry	M
Clause 4 Tensile strength-Wet	M
Clause 4 Liquid penetration-Water Resistance	M
Clause 4 Cleanliness microbial/Bioburden	M
Clause 4 Microbial Penetration-Dry	M
Clause 4 Microbial penetration-Wet	M
Clause 4 Particle release	M

Remark: M=Meet EN 13795-1:2019 standard performance requirement

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)

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Testing Center

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Test Result

Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns
(EN 13795-1:2019)

Clause 4 Bursting strength-Dry*
(EN ISO 13938-1: 1999; Dry state; Test area: 10cm^2)

Material

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	117	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	97.0		
3	104		
4	112		
5	108		

Sleeve seam

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	134	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	128		
3	132		
4	131		
5	130		

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Clause 4 Bursting strength-Wet*

(EN ISO 13938-1: 1999; Dry state; Test area: 10cm^2)

Material

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	69.4	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	99.4		
3	87.3		
4	74.9		
5	92.3		

Sleeve seam

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	134	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	126		
3	128		
4	133		
5	131		

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Clause 4 Tensile strength-Dry

(EN 29073-3:1992; Dry state; The distance between the clamps: 200mm; Rate: 100mm/min)
(EN 29073-3:1992 eqv ISO 9073-3:1989)

Material

Sample	Length (N)	Width (N)	Requirement (N)	Conclusion
1	48.1	70.9	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	54.0	78.6		
3	55.7	72.5		
4	52.8	68.6		
5	49.7	75.5		

Sleeve seam

Sample	(N)	Requirement (N)	Conclusion
1	38.0	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	34.2		
3	34.0		
4	36.8		
5	38.3		

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Clause 4 Tensile strength-Wet

(EN 29073-3: 1992; Wet state. The distance between the clamps: 200mm; Rate: 100mm/min)
(EN 29073-3:1992 eqv ISO 9073-3:1989)

Material

Sample	Length (N)	Width (N)	Requirement (N)	Conclusion
1	47.3	75.7	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	48.8	69.0		
3	46.8	79.1		
4	45.1	73.8		
5	47.2	73.2		

Sleeve seam

Sample	(N)	Requirement (N)	Conclusion
1	41.2	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	38.4		
3	37.4		
4	37.9		
5	37.4		

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Clause 4 Liquid penetration-Water Resistance

(EN ISO 811: 2018; Rate of increase of water pressure:10cm/min; temp. of distilled water:20.0℃; Face side to water)

Material

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	＞20	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	＞20		
3	＞20		
4	＞20		
5	＞20		

Sleeve seam

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	＞20	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	＞20		
3	＞20		
4	＞20		
5	＞20		

Clause 4 Cleanliness microbial/Bioburden

(EN ISO 11737-1: 2018; Membrane Filtration Method)

Sample	total plate count ($CFU/100cm^2$)	Requirement ($CFU/100cm^2$)	Conclusion
1	30	≤300 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	240		
3	66		
4	33		
5	270		

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Clause 4 Microbial Penetration-Dry*

(EN ISO 22612:2005,The fourth generation of spores of bacillus subtilis ATCC 9372, The concentration of the spores:1.8×10^8 CFU/g talcum powder,Sample:12,Vibration frequency:20800 times/min,Vibration time:30min)

Material

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	0	≤300 (Surgical gown: standard performance less critical product area) EN 13795-1:2019	Pass
2	0		
3	0		
4	0		
5	0		
6	0		
7	0		
8	0		
9	0		
10	0		

Sleeve seam

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	0	≤300 (Surgical gown: standard performance less critical product area) EN 13795-1:2019	Pass
2	0		
3	0		
4	0		
5	0		
6	0		
7	0		
8	0		
9	0		
10	0		

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Clause 4 Microbial penetration-Wet*

(EN ISO 22610:2006,Temp:24.5℃,RH:56.0% ,The distance of agar to plates brim:3mm, Carrier material:30μm polyurethane (PU))

Material

Sample	Barrier index	Requirement Barrier index	Conclusion
1	6.0	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	6.0		
3	6.0		
4	6.0		
5	6.0		

Sleeve seam

Sample	Barrier index	Requirement Barrier index	Conclusion
1	6.0	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	6.0		
3	6.0		
4	6.0		
5	6.0		

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Clause 4 Particle release*

(EN ISO 9073-10: 2004; Size of particles counted: 3um-25um)
(EN ISO 9073-10:2004 idt ISO 9073-10:2003)

Material

Size of particles counted (μm)	Sample		Measured value Coefficient of linting log_{10}	Requirement Coefficient of linting log_{10}	Conclusion
3～25	A: Face	1	2.6	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	**Pass**
		2	2.3		
		3	2.5		
		4	2.6		
		5	2.3		
	A: Back	1	2.6		
		2	2.6		
		3	2.6		
		4	2.7		
		5	2.6		

Sleeve seam

Size of particles counted (μm)	Sample		Measured value Coefficient of linting log_{10}	Requirement Coefficient of linting log_{10}	Conclusion
3～25	A: Face	1	2.3	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	**Pass**
		2	2.0		
		3	2.2		
		4	2.3		
		5	2.0		
	A: Back	1	2.9		
		2	2.8		
		3	2.9		
		4	3.0		
		5	2.8		

*This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment).

检验检测专用章 Inspection & Testing Services
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center

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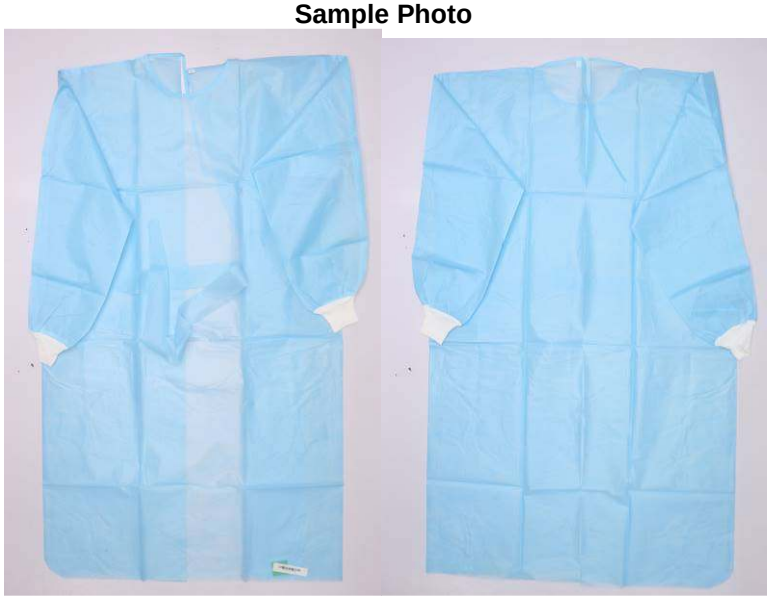
Sample Photo



Face Back

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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Certification Department

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XINLE HUABAO MEDICAL
PRODUCTS CO., LTD.
Dongguan, Cheng'an Town
050701 XINLE CITY, HEBEI PROVINCE
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date October 31, 2019

Application for : QMS
Certificate No. : SX 60143175 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60143175 0001
replacing the previous certificate.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

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LGA Products GmbH

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60143175 0001
Report No.: 16806100 005

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

Scope:

Products:

- Non-woven Products
- Non-woven and PE composited Products
- PE Products
- Paper Products
- PE and Paper composited Products

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Prüfstelle

Date: 2019-10-31

Jing Zhang

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Disposable Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-10-31
Certificate Registration No.:	SX 60143175 0001
An audit was performed. Report No.:	16806100 005
This Certificate is valid until:	2022-07-07

Certification Body

DAkkS
Deutsche
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D-ZM-14169-01-02

Date 2019-10-31

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Jing Zhang

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