No.	Standard No.	Edition	Name
1	EN 455-1	2000	Medical Gloves For Single Use Part 1: Requirements and testing for freedom from holes
2	EN 455-2	2015	Medical Gloves For Single Use Part 2: Requirements and testing for physical properties
3	EN 455-3	2015	Medical Gloves For Single Use Part 3: Requirements and testing for biological evaluation
4	EN 455-4	2015	Medical Gloves For Single Use Part4:Requirement and testing for shelf determination
5	EN 556-1	2001/AC:2006	Sterilisation of medical devices- Requirements for medical device to be designated ' STERILE' – Part 1:Requirements for terminally sterilised medical devices
6	ENISO15223-1	2016	Graphical symbols for use in the labeling of medical devices
7	EN 1041	2008	Information supplied by the manufacturer with medical devices
8	ISO 11737-1	2006	Sterilisation of medical devices- Microbiological methods – Part 1: Determination of a population of microorganisms on products
9	ISO 11737-2	2009	Sterilization of medical devices. Estimation of the population of micro-organisms on product. Part 2: Guidance.
10	ISO 11737-3	2004	Estimation of the population of micro-organisms on product. Part 3: Guide to the methods for validation of microbiological techniques.
11	MDD93/42/EEC	1993/AC:2007	Medical Devices Directive
12	EN ISO 13485	2016	The Requirements of the Medical Devices' Quality Controlling System for Laws and Regulations
13	ENISO 14971	2012	Medical devices - application of risk management to medical devices
14	ENISO 10993-1	2009	Biological evaluation of medical devices Part 1: Evaluation and testing
15	ENISO 10993-5	2009	Biological evaluation of medical devices Part 5: Cytotoxiciy tests – in vitro tests
16	ENISO10993-10	2009	Biological evaluation of medical devices Part 10: Stimulation and sensitization tests
17	ENISO 14155	2011	Clinical investigation of medical devices
18	ISO 11607-1	2006	Packaging for terminally sterilized medical devices Part 1
19	ISO 11607-2	2006	Packaging for terminally sterilized medical devices Part 2
20	ISO 11346	2014	Rubber,vulcanized or thermoplastic—Estimation of life and Maximum temperature of use
21	Meddev2.12-1 rev8	2013	Guidelines on A Medical Devices Vigilance System
22	EN ISO 11137-1	2015	Validation and routine control of a sterilization process for medical devices – radiation
23	Meddev.2.7.1-rev.4	2016	Evaluation of clinical date
24	Meddev2.12/2 rev2	2012	Post market clinical follow-up studies
25	EN 62366-1	2015	Medical devices - application of usability engineering to medical devices
26	EN ISO11607-1	2017	Packing for terminally sterilized medical devices part 1: Requirements for materials, sterile barrier systems and packaging systems
27	EN ISO11607-2	2006	Packing for terminally sterilized medical devices Part 2: validation requirements for forming,sealing and assembly process

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

Hebei Tianshuo Medical Products Co.,Ltd.
Dabu Village,Xiong County, Baoding, 071800 Hebei, China.

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Sterile Latex Surgical Gloves

der Klasse: /
of class: /
de la classe: /
di classe:

IIa

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Richtlinie 93/42/EWG Anhang V
Directive 93/42/EEC Annex V
Directive 93/42/CEE Annexe V
Direttiva 93/42/CEE senza Allegato V

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

DD 60128541 0001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

BaoDing 2018.5.2

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

1/1

Declaration of Conformity

MANUFACTURER:	**HEBEI TIANSHUO MEDICAL PRODUCTS CO.,LTD DABU VILLAGE,XIONG COUNTY , Baoding city Heibei Province, 071800, P.R. China.**
MEDICAL DEVICE:	**LATEX EXAMINATION GLOVES**
CLASSIFICATION - ANNEX IX:	*Class* Ⅰ*, （rule 5 of ANNEX IX）
CONFORMITY ASSESSMENT ROUTE:	*MDD/93/42/EEC Ax.VII*

WE, THE MANUFACTURER, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	***ISO 13485: 2016, EN ISO 14971: 2012, EN ISO 11137-1: 2006, EN ISO 11137-2: 2017; EN ISO 11137-3: 2006; EN ISO 11607-1: 2006, EN ISO 11607-2: 2006, EN ISO 10993-1: 2009, EN ISO 10993-5: 2009; EN ISO 10993-11: 2009; EN 556-1: 2001; EN1041: 2008, EN ISO15223-1: 2012, EN 455-1: 2000, EN 455-2: 201, EN 455-3: 2015, EN 455-4: 2009***
NOTIFIED BODY:	**TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR. 65 - 80339 MÜNCHEN, GERMANY**
IDENTIFICATION NUMBER	CE **0197**
(EC) CERTIFICATE(S):	
EC REP ***EUROPEAN REPRESENTATIVE:***	**Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse,80, D-20537, Hamburg, Germany Tel: 0086-021-65951371，0049-40-2513175，Fax: 0049-40-255726**
START OF CE-MARKING:	**SEP.1.2007**

PLACE, DATE OF DECLARATION:	***BAODING, 2017-06-06***
SIGNATURE:	
	NAME: MR. ZHEBO ZANG **POSITION: MANAGERING DIRECTOR**
EXP. DATE:	**2022-12-20**

Test Report

No.: SHHL1708047269PK Date: AUG. 25, 2017 Page: 1 of 11

HEBEI BAIMEI LATEX PRODUCTS CO., LTD.
DABU, VILLAGE, XIONG COUNTY, BAODING HEBEI PROVINCE, CHINA

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

Sample Description	: STERILE LATEX SURGICAL GLOVES
Sample No.	: 14S17014902
Batch No.	: 20170625
Manufacturer	: HEBEI BAIMEI LATEX PRODUCTS CO., LTD.
Sample Receiving Date	: AUG. 14, 2017
Testing Period	: AUG. 14, 2017 TO AUG. 25, 2017
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: TRANSPORTATION TEST (AS PER ASTM D4169-16 & DISTRIBUTION CYCLE-13 AND CLIENT'S REQUIREMENT)
Test Result(s)	: FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

****

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

Yomoro Gu
Authorized Signatory

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Test Conducted:

1. **Shipping marks (Main mark)**

2. **Description of packaged-product**

a) External container size (mm): length 670 X width 255 X depth 410

b) Gross weight of packaged-product tested (kg): 14.73

c) Shipping carton

Forms	:	Double wall corrugated board
Box Makers Certificate	:	No
joint	:	Stitch joint & Double & Diagonal
Closed With	:	Pressure sensitive tape & Fixation strap
Style	:	Top opening

d) Internal packing(details please see photos)

— The product was enclosed in a sterile bag.

— Total of fifty above units were stacked together orderly, then were set in a retail box.

— Ten retail boxes with contents were divided to two layers and stacked together, then they were packed into a shipping carton, finally were secured by fixation straps.

3. **Transportation test (As Per ASTM D4169-16 & Distribution Cycle-13 and client's requirement)**

Sample size: One carton with contents

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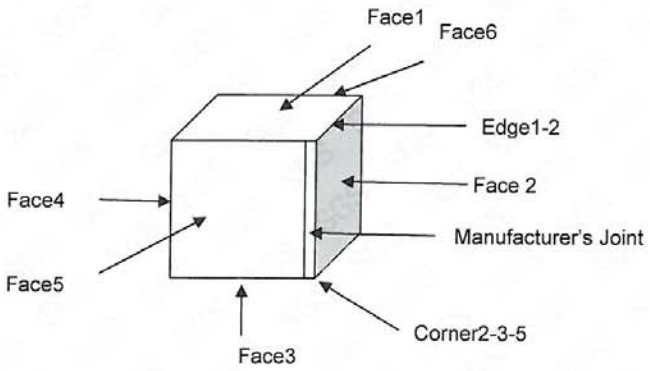
a)Schedule A Handling Manual Drop test



Drop Sequence Number	Drop Height (mm)	Orientation of packaged-product		
No.1	330	Face(Top)	Face 1	Top
No.2	330	Edge	Edge 3-5	Adjacent bottom edges
No.3	330	Edge	Edge 2-3	
No.4	330	Corner	Corner 2-3-5	Diagonally opposite bottom corners
No.5	330	Corner	Corner 3-4-6	
No.6	330	Face (Bottom)	Face 3	Bottom

(From 9.1 to 18.1kg. Assurance level II)

Inspection before drop: No
Inspection after drop: No

b) Schedule C Vehicle stacking test

For vehicle stacking made up of identical shipping units, load the shipping units to the computed load value, as calculated below.

Calculate Stack load (for vehicle stacking made up of identical shipping unit)	Stack Load = M x J x (H-h) /h x F =5643.89 N
M: mass of one shipping unit or individual container, kg	14.73
J:9.8 N/kg	9.8
H: Maximum height (m) of package stack in transit	2.7
h: Height of shipping unit or individual container,(m)	0.41

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center
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	F : A factor to account for the combined effect of individual factors (Assurance level II F=7.0)	7.0
	Inspection before compression: No **Inspection after compression:** No	
c) Schedule F Loose-load vibration test	The shipping unit is subject to a "repetitive bounce" test in the three mutually perpendicular axes for a total duration of **40** minutes. (Assurance Level II) Repetitive Shock Test Method: Rotary Motion Frequency: 210 CPM Dwell time distributed 50% along normal vertical shipping axis (bottom side) and remaining 50% evenly along all other possible shipping orientations (two side faces adjacent to bottom). **Inspection before vibration:** No **Inspection after vibration:** No	

d) Schedule E Vehicle vibration test

Truck vibration:

Frequency (Hz)	Power Spectral Density Level (G^2/Hz) Low Level	Power Spectral Density Level (G^2/Hz) Medium Level	Power Spectral Density Level (G^2/Hz) High Level
1	0.0004	0.00072	0.00072
3	0.010	0.018	0.030
4	0.010	0.018	0.030
6	0.00040	0.00072	0.0012
12	0.00040	0.00072	0.0012
16	0.0020	0.0036	0.0060
25	0.0020	0.0036	0.0060
30	0.00040	0.00072	0.0012
40	0.0020	0.0036	0.0060
80	0.0020	0.0036	0.0060
100	0.00020	0.00036	0.00060

	200 | 0.000010 | 0.000018 | 0.000030 Overall G_{rms} | 0.40 | 0.54 | 0.70 Duration(minutes) | 40 | 15 | 5 The duration is distributed evenly between three orientations. **Air vibration:** Frequency (Hz) | Power Spectral Density Level(G^2/Hz), (Assurance Level Ⅱ) 2 | 0.0002 12 | 0.01 100 | 0.01 300 | 0.00001 Overall (g rms) | 1.05 Duration (minutes) | 120 The duration is distributed evenly between three orientations. **Inspection before vibration: No** **Inspection after vibration: No**
e) Schedule J Concentrated impact test	Not applicable as standard requirement
f) Schedule A Handling Manual Drop test	**Drop Sequence Number** | **Drop Height (mm)** | **Orientation of packaged-product** No.1 | 330 | Edge | Edge 2-5 | Vertical edge No.2 | 330 | Face | Face 2 | Adjacent faces No.3 | 330 | Face | Face 5 No.4 | 330 | Corner | Corner 1-2-5 | One top corner and No.5 | 330 | Edge | Edge 1-2 | one adjacent top edge No.6 | 660 | Face | Face 3 | Bottom(Most likely for a drop occur) (From 9.1 to 18.1kg. Assurance level Ⅱ) **Inspection before drop:** No **Inspection after drop:** Yes

Test Result: Satisfactory

No visible damage was found on the outer carton and products of sample after performing ASTM D4169-16 DC-13 test as per client's requirement

Remark: Slight abrasion and deformation were found on the retail boxes after test.

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