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YHUK Product Certificate Document

**HenChan Vinyl Gloves**

Date: 2020/04/25



## Test Report

No.: SHHG1302005804MD

Date: MAR.12,2013

Page: 1 of 4

ZIBO HENGCHANG PLASTIC & RUBBER PRODUCTS CO., LTD  
SCIENCE & TEC. PARK OF ZIBO, SHANDONG PROVINCE, P.R.CHINA

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

Sample Description : DISPOSABLE VINYL GLOVES  
SGS Ref. No. : QDHG201300378  
Style/ Item No. : M  
Manufacturer : ZIBO HENGCHANG PLASTIC & RUBBER PRODUCTS  
CO., LTD  
Country of Origin : CHINA  
Sample Receiving Date : FEB.25,2013  
Testing Period : FEB.25,2013 TO MAR.12,2013  
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT  
Test Requested : WIDTH AND FORCE AT BREAK (EN 455-2-2009+A12011  
MEDICAL GLOVES FOR SINGLE USE – PART 2:  
REQUIREMENTS AND TESTING FOR PHYSICAL  
PROPERTIES CLAUSE 4.2 AND CLAUSE 5.3)  
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 Ltd.

Oliva Kou  
Operation Manager

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### Test Conducted:

EN 455-2-2009+A12011 Medical gloves for single use – part 2: Requirements and testing for physical properties

Number of test sample : 13 Piece(s)  
 Type : examination/procedure gloves  
 Material : Vinyl  
 Test Result : Pass

#### 1. Width (Clause 4.2)

Size	Medium												
Width(mm)	96	97	95	96	97	98	97	97	95	95	95	96	97

Median value: 96mm

Requirements: see table 1

Table 1 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	$\geq 240$	$\leq 80$
Small		$80 \pm 10$
Medium		$95 \pm 10$
Large		$110 \pm 10$
Extra Large		$\geq 110$

Result: Pass

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### 2. Force at break (Clause 5.3)

Size	M												
Force at break(N)	4.93	4.74	4.26	4.11	4.43	4.86	4.89	4.40	4.75	5.04	4.60	4.84	4.26

Median value: 4.74N

Requirements: see table 2

Table 2 Median values of force at break

	Force at break (in N)				
	Surgical gloves		Examination/procedure gloves		
	a)	b)	c)	d)	e)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥9.0	≥9.0	≥6.0	≥6.0	≥3.6
a) Requirements for gloves made from natural rubber latex. b) Requirements for gloves made from all other elastomeric materials, e.g. polychloroprene, synthetic polyisoprene, nitrile styrene block copolymers, polyurethane. c) Requirements for gloves made from elastomeric materials except nitrile, e.g. natural rubber latex, polychloroprene, synthetic polyisoprene, styrene block copolymers, polyurethane. d) Requirements for gloves made from nitrile. e) Requirements for gloves made from thermoplastic materials(e.g. polyvinylchloride, polyethyleng).					

Result: Pass

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Sample Photo:

	Test sample	

\*\*\*End of Report\*\*\*

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## Test Report

No. TSNHG1900035301

Date: 11 Jan 2019

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SHANDONG HENGCHANG MEDICAL TECHNOLOGY CO., LTD

SCIENCE TEC PARK OF ZIBO IN ZHANGDIAN, ZIBO CITY 255087, SHANDONG CHINA.

The following sample(s) was/were submitted and identified on behalf of the clients as : CLEAR VINYL GLOVE

SGS Job No. : QDHL1901000062OT - QD

Date of Sample Received : 07 Jan 2019

Testing Period : 07 Jan 2019 - 11 Jan 2019

Test Requested : Selected test(s) as requested by client.

Test Method : Please refer to next page(s).

Test Results : Please refer to next page(s).

Conclusion : Based on the performed tests on submitted sample(s), the results of Lead, Mercury, Cadmium, Hexavalent chromium, Polybrominated biphenyls (PBBs), Polybrominated diphenyl ethers (PBDEs) and Phthalates such as Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), and Diisobutyl phthalate (DIBP) comply with the limits as set by RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU.

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

Reabeca Zhou  
Approved Signatory



TSNHG1900035301



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Test Results :

### Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	TSN19-000353.001	white translucent plastic gloves

Remarks :

- (1) 1 mg/kg = 0.0001%
- (2) MDL = Method Detection Limit
- (3) ND = Not Detected ( < MDL )
- (4) "-" = Not Regulated

### RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU

Test Method : With reference to IEC 62321-5:2013, IEC 62321-4:2013+AMD1:2017, IEC 62321-7-2:2017, IEC 62321-6:2015 and IEC 62321-8:2017, analyzed by ICP-OES, UV-Vis and GC-MS.

Test Item(s)	Limit	Unit	MDL	001
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1000	mg/kg	2	ND
Mercury (Hg)	1000	mg/kg	2	ND
Hexavalent Chromium (Cr(VI))	1000	mg/kg	8	ND
Sum of PBBs	1000	mg/kg	-	ND
Monobromobiphenyl	-	mg/kg	5	ND
Dibromobiphenyl	-	mg/kg	5	ND
Tribromobiphenyl	-	mg/kg	5	ND
Tetrabromobiphenyl	-	mg/kg	5	ND
Pentabromobiphenyl	-	mg/kg	5	ND
Hexabromobiphenyl	-	mg/kg	5	ND
Heptabromobiphenyl	-	mg/kg	5	ND
Octabromobiphenyl	-	mg/kg	5	ND
Nonabromobiphenyl	-	mg/kg	5	ND
Decabromobiphenyl	-	mg/kg	5	ND
Sum of PBDEs	1000	mg/kg	-	ND
Monobromodiphenyl ether	-	mg/kg	5	ND
Dibromodiphenyl ether	-	mg/kg	5	ND
Tribromodiphenyl ether	-	mg/kg	5	ND
Tetrabromodiphenyl ether	-	mg/kg	5	ND
Pentabromodiphenyl ether	-	mg/kg	5	ND
Hexabromodiphenyl ether	-	mg/kg	5	ND



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Test Item(s)	Limit	Unit	MDL	001
Heptabromodiphenyl ether	-	mg/kg	5	ND
Octabromodiphenyl ether	-	mg/kg	5	ND
Nonabromodiphenyl ether	-	mg/kg	5	ND
Decabromodiphenyl ether	-	mg/kg	5	ND
Dibutyl phthalate (DBP)	1000	mg/kg	50	ND
Butyl benzyl phthalate (BBP)	1000	mg/kg	50	ND
Bis (2-ethylhexyl) phthalate (DEHP)	1000	mg/kg	50	ND
Diisobutyl Phthalates (DIBP)	1000	mg/kg	50	ND

### Notes :

- (1) The maximum permissible limit is quoted from RoHS Directive (EU) 2015/863. IEC 62321 series is equivalent to EN 62321 series  
[http://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP\\_ORG\\_ID,FSP\\_LANG\\_ID:1258637,25](http://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP_ORG_ID,FSP_LANG_ID:1258637,25)
- (2) On 4 June 2015, Commission Directive (EU) 2015/863 was published in the Official Journal of the European Union (OJEU) to include the phthalates BBP, DBP, DEHP and DIBP into ANNEX II of the Rohs Recast Directive. The new law restricts each phthalate to no more than 0.1% in each homogeneous material of an electrical product.
- (3) The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.
- (4) The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021.
- (5) The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.



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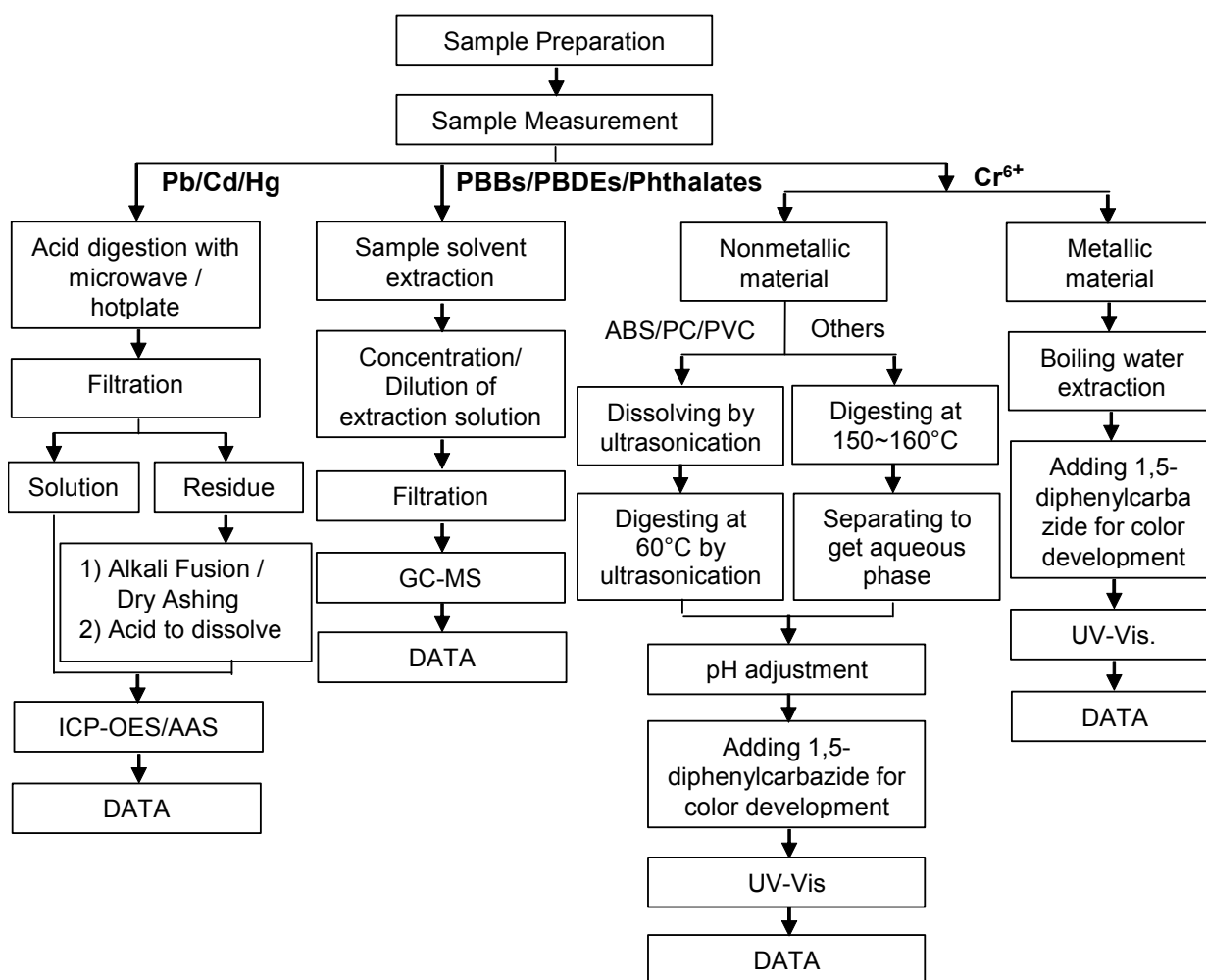
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### ATTACHMENTS

#### Pb/Cd/Hg/Cr<sup>6+</sup>/PBBs/PBDEs/Phthalates Testing Flow Chart

- 1) These samples were dissolved totally by pre-conditioning method according to below flow chart.  
(Cr<sup>6+</sup> and PBBs/PBDEs /Phthalates test method excluded)



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Sample photo:



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**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Shandong Hengchang Medical  
Technology Co., Ltd.  
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Zibo  
255087 Shandong  
China**

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

**Manufacture and Distribution of Disposable Vinyl Gloves**

**(see attachment for additional sites 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: 2018-05-25

Certificate Registration No.: SX 60129049 0001

An audit was performed. Report No.: 16801322 007

This Certificate is valid until: 2020-09-28

Certification Body



Date 2018-05-25



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