TEST REPORT

Product.....:	Hand Sanitizer
Model.....:	20ml , 30ml , 50ml , 53ml , 60ml , 65ml , 90ml , 100ml , 120ml, 150ml, 180ml , 200ml , 236ml , 250ml, 350ml , 400ml ,500ml , 600ml ,800ml, 1L
Trademark.....:	N/A
Prepared For.....:	ZHEJIANG MEIZHIYUAN COSMETICS CO.,LTD Yidong Industrial area, Yiwu city, Zhejiang Province
Prepared By .....:	Shenzhen Boke Testing Co., Ltd. Floor 2, Complex Building, No. 438 Industrial Park, Donghuan Road, Xiner Community, Xinqiao Street, Bao'an District, Shenzhen, GuangDong, China Mail:admin@boke-lab.com Web: http://www.boke-lab.com Tel.:0755-27782934

TEST REPORT

EN 1499

Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)

Report Number.....:	BOKE-200301127S
Date of issue.....:	Mar. 31, 2020
Total number of pages.....:	12 pages
Testing Laboratory.....:	**Shenzhen Boke Testing Co., Ltd.**
Address.....:	Floor 2, Complex Building, No. 438 Industrial Park, Donghuan Road, Xiner Community, Xinqiao Street, Bao'an District, Shenzhen, GuangDong, China
Applicant's name.....:	**ZHEJIANG MEIZHIYUAN COSMETICS CO.,LTD**
Address.....:	Yidong Industrial area, Yiwu city, Zhejiang Province
Test specification:	
Standard.....:	**EN 1499:2013**
Test procedure.....:	N/A
Non-standard test method.....:	N/A
Test Report Form No.....:	**EN 1499A**
Test Report Form(s) originator.....:	BOKE
Master TRF.....:	2013-04-05

Test item description.....:	Hand Sanitizer
Trademark.....:	N/A
Manufacturer.....:	**ZHEJIANG MEIZHIYUAN COSMETICS CO.,LTD** Yidong Industrial area, Yiwu city, Zhejiang Province
Model/Type reference.....:	20ml, 30ml, 50ml, 53ml, 60ml, 65ml, 90ml , 100ml , 120ml, 150ml, 180ml, 200ml, 236ml, 250ml, 350ml, 400ml, 500ml , 600ml, 800ml, 1L

Name and address of the testing laboratory:

Shenzhen Boke Testing Co., Ltd.
Floor 2, Complex Building, No. 438 Industrial Park,
Donghuan Road, Xiner Community, Xinqiao Street,
Bao'an District, Shenzhen, GuangDong, China

Date of Test.....: Mar. 25, 2020- Mar. 31, 2020

Tested by (name + signature).....: Len Xue

Reviewed by (name + signature)..... : Mossi Pan

Approved by (name + signature)..... : Levi Lee

List of Attachments (including a total number of pages in each attachment):
Attachment I: Product photos (1 pages)

Summary of testing:
The products covered by this report have been tested complying with the applicable requirements of this standard.

Tests performed (name of test and test clause):	**Testing location:**
-EN 1499:2013	Shenzhen Boke Testing Co., Ltd. Floor 2, Complex Building, No. 438 Industrial Park, Donghuan Road, Xiner Community, Xinqiao Street, Bao'an District, Shenzhen, GuangDong, China

Summary of compliance with National Differences:
List of countries addressed:
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☒ **The product fulfils the requirements of EN 1499:2013**

Possible test case verdicts:	
- test case does not apply to the test object..... :	N/A
- test object does meet the requirement..... :	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	
Date of receipt of test item..... :	Mar. 25, 2020
Date (s) of performance of tests..... :	Mar. 25, 2020- Mar. 31, 2020
General remarks:	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. **Throughout this report a ☒ comma / ☐ point is used as the decimal separator.** **Clause numbers between brackets refer to clauses in EN 1499:2013**	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided.....:	☐ **Yes** ☒ **Not applicable**
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies).....:	Same as applicant
General product information: --	

EN 1499:2013			
Cl.	Requirement – Test	Result	Verdict
	CONSTRUCTION		P
5	Test methods		P
5.1	Principle		P
	Hands of volunteers are artificially contaminated with test organisms. The number of test organisms released from their fingertips into sampling fluids is assessed before and after the hygienic handwash. The ratio of the two resulting values represents a measure for the antimicrobial activity of the product tested. The necessary precision is achieved by repeating the test on 12 to 15 volunteers. To compensate for extraneous influences, it is compared with the reduction obtained by a reference handwash which is performed with the same volunteers.on the same day and under comparable environmental conditions		P
5.2	Materials and reagents		P
5.3	Apparatus and glassware		P
5.3.1	General		P
	Sterilise all glassware and parts of the apparatus that will come into contact with the culture media and reagents or the sample, except those that are supplied sterile by one of the following methods:		P
	a) by moist heat. in the autoclave [5.3.2.1 a);		P
	b) by dry heat, in the hot air oven [5.3.2.1 b)		N/A
5.3.2	Usual microbiological laboratory equipment2) In particular, the following:		--
5.3.2.1	Apparatus for sterilisation		--
5.3.2.2	Water baths		--
5.3.2.3	Incubator		--
5.3.2.4	PH-meter		--
5.3.2.5	Stopwatch		--
5.3.2.6	Shakers		--
5.3.2.7	Membrane filtration apparatus		--
5.3.2.8	Refrigerator	5℃	--

EN 1499:2013			
Cl.	Requirement – Test	Result	Verdict
5.3.2.9	Graduated pipettes		--
5.3.2.10	Petri dishes (plates	94mm	--
5.3.2.11	Glass beads	3.3mm	--
5.3.2.12	Volumetric flasks		--
5.3.2.13	Spreader	glass	--
5.3.2.14	Container of sufficient capacity to immerse two hands vertically up to the mid-metacarpals simultaneously in 2 L of contamination fluid		--
5.3.2.15	Two bottles of at least 1L capacity		--
5.4	Preparation of test organism suspensions and product test solutions		P
5.4.1	Test organism suspensions (test and validation suspension)		P
5.4.1.1	General		P
5.4.1.2	Preservation and stock cultures of test organisms		P
	The test organism and its stock cultures shall be prepared and kept in accordance with EN 12353.		P
5.4.1.3	Working culture of test organisms	48h cultivate	P
5.4.1.4	Test suspension ("N') / Contamination fluid		P
5.4.1.5	Validation suspension ("Nv"", "NvB")		P
5.4.1.6	Incubation and counting of the test and the validation suspensions		P
5.4.2	Product test solutions		P
5.5	Procedure for assessing the bactericidal activity of the product on volunteers' hands		P
5.5.1	General		P
5.5.1.1	Experimental conditions		P
	a) temperature:The temperature for the control and validation of the neutralizer and the test suspension (contamination fluid)is 20 ° C±1° C.		P
	b) contact time t (in s):The contact time to be tested is to be chosen according to the manufacturer's recommendation, but not shorter than 30 s and not longer than 60 s. The final rinse is not regarded as part of the		P

EN 1499:2013			
Cl.	Requirement – Test	Result	Verdict
	contact time. For the.reference handwash, the contact time is 60 sThe allowed deviation for each chosen contact time is ±5 s		
5.5.1.2	Neutralization		P
5.5.1.3	Equilibration of temperature		P
	Prior to testing, equilibrate all reagents [product test solutions (5.4.2), diluted soft soap (5.2.2.6), test suspension (5.4.1.4), validation suspension (5.4.1.5), TSB (5.2.2.4), the neutralizer (5.2.2.5) and -if necessary - hard water (5.2.2.7) to the test temperature of 20 C using the water bath (5.3.2.2) controlled at 20 ° C. Check that the temperature of the reagents is stabilised at 20 ° C.		P
5.5.1.4	Selection of volunteers		P
	The test shall be performed on 12 to 15 healthy persons who have hands with healithy skin, without cuts or abrasions, and with short and clean fingernails. Although, in general, age is not a limiting factor, volunteers should be at least 18 years of age. As it may happen that values of volunteers cannot be used for calculation, it is recommended to do the test rather with a higher number than 12 volunteers. On the day of the test, volunteers should not wear any jewellery or other items on the hands and wrists.	12 volunteers, >18 years of age	P
5.5.1.5	Experimental design		P
	For testing a single product, a cross-over desian is used. The volunteers are randomly divided into two groups of approximately the same size. Group 1 uses the reference hygienic handwash (RP, 5.5.3.3.2), group 2 the product under test (PP, 5.5.3.3.3).The test is then repeated on the same day with group 1 using the handwash procedure with the test product and group 2 using the reference handwash procedure. Before every reference handwash procedure and every handwash		P

EN 1499:2013			
Cl.	Requirement – Test	Result	Verdict
	procedure with the product under test, the procedures described in 5.5.3.1 and 5.5.3.2 shall be carried out.		
5.5.2	Neutralization -control and validation		P
5.5.2.1	Neutralizer control"B" - verification of the absence of toxicity of the neutralizer		P
5.5.2.2	Method validation "C"		P
5.5.3	Test procedure with volunteers		P
5.5.3.1	Application of the contamination fluid		P
5.5.3.2	Sampling of the test organisms before treatment ("Prevalue")		P
5.5.3.3	Hygienic handwash procedure		P
5.5.4	Incubation and counting of the test mixture and the control and validation mixtures		P
	For incubation and counting of the test mixture and the control and validation mixtures, the procedure is as follows		P
	a) Incubate (5.3.2.3) the plates for 20 h to 24 h. Discard any plates which are not countable (for any reason).Count the plates and determine the number of cfu. Incubate the plates for a further 20 h to 24 h. Do not recount plates which no longer show well separated colonies. Recount the remaining plates. If the number has increased, use only the higher number for further evaluation.		P
	b) Note for each plate the exact number of colonies but record "> 330" for any counts higher than 330 and determine the Vc-values accordina to 5.6.2.2.		P
	C) Calculate the numbers of cfu/ml in the test mixtures of prevalue and postvalue (5.6.2.6) and in the validation mixtures B and C using the method given in 5.6.2.4 and 5.6.2.5. Verify according to 5.7.		P
5.6	Experimental data and calculation		P
5.6.1	Explanation of terms and abbreviations		--
5.6.2	Calculation		--
5.6.2.1	General		--

EN 1499:2013			
Cl.	Requirement – Test	Result	Verdict
	The first step in the calculation is the determination of the Vc-values. The second step is the calculation of N,Nv, Nv0, NvBand C. The third step is the calculation of the reduction R (5.6.2.6)		P
5.6.2.2	Determination of Vc-values	counting bacteria on agar plates are :173	P
5.6.2.3	Calculation of N		P
	is the number of cells per ml in the test suspension / contamination fluid (5.4.1.4: 5.6.1.1).Since the two dilutions of the test suspension (5.4.1.4 in connection with 5.4.1.6) are evaluated, calculate the number of cfu/ml as the weighted mean count using the following formula $N = \frac{C}{(n_1 + 0{,}1\, n_2)\ d}$		P
5.6.2.4	Calculation of NV, NV0 and NVB		P
5.6.2.5	Calculation of B and C		P
	Calculate B and C using the following formula: $B, C = c/n$		P
5.6.2.6	Calculation of the lg reduction R (lg pre-value minus lg post-value)		P
5.7	Verification of the methodology - Test validation		P
5.7.1	Acceptance criteria for test results		P
	Only if the results of the test procedure fulfil the following requirements, shall they be accepted for further evaluation, otherwise the test shall be repeated.		P
	a) A complete set of results from at least 12 volunteers shall be available. All complete sets of results shall be used for further evaluation.		P
	b) The overall means of the la prevalues for RP and PP shall be both at least 5.00		P
	c) The absolute difference of mean differences between la reductions of RP and		P

EN 1499:2013			
Cl.	Requirement – Test	Result	Verdict
	PP of aroup BP→PP and group PP -BP shall be less than 2.00.		
	d) The criteria of 5.7.2 and 5.7.3 shall be fulfilled.		P
5.7.2	Control of weighted mean counts		P
5.7.3	Basic limits	Below the limits for N,NV, NV0 and NVB	P
5.8	Statistical evaluation (signiticance testing), expression of results and precision		P
	If the quality of the data has been found to be acceptable (5.7.1), they shall be used for the evaluation of the product(s) under test by applying the following pass criterion:PP (procedure with product) shall be larger than RP (procedure with reference).		P
5.9	Conclusion		P
	A product which has fulfiled the requirements (Clause 4 and 5.8) is deemed suitable to be used as medical hygienic handwash.		P
5.10	Test report		P
	Annex A(normative)Standard handwash procedure		P

Bactericidal effect on experimental bacteria				
Test voltage applied between:	the average bactericidal rate (%) and its range at different time (s)			
Test bacteria	30s	60s	120s	300s
E. coli	99.4%	99.6%	99.7%	99.9%
Staphylococcus aureus	99.4%	99.6%	99.8%	99.9%
Candida albicans	99.4%	99.5%	99.7%	99.9%
Supplementary information: --				

Attachment I: Photo document.

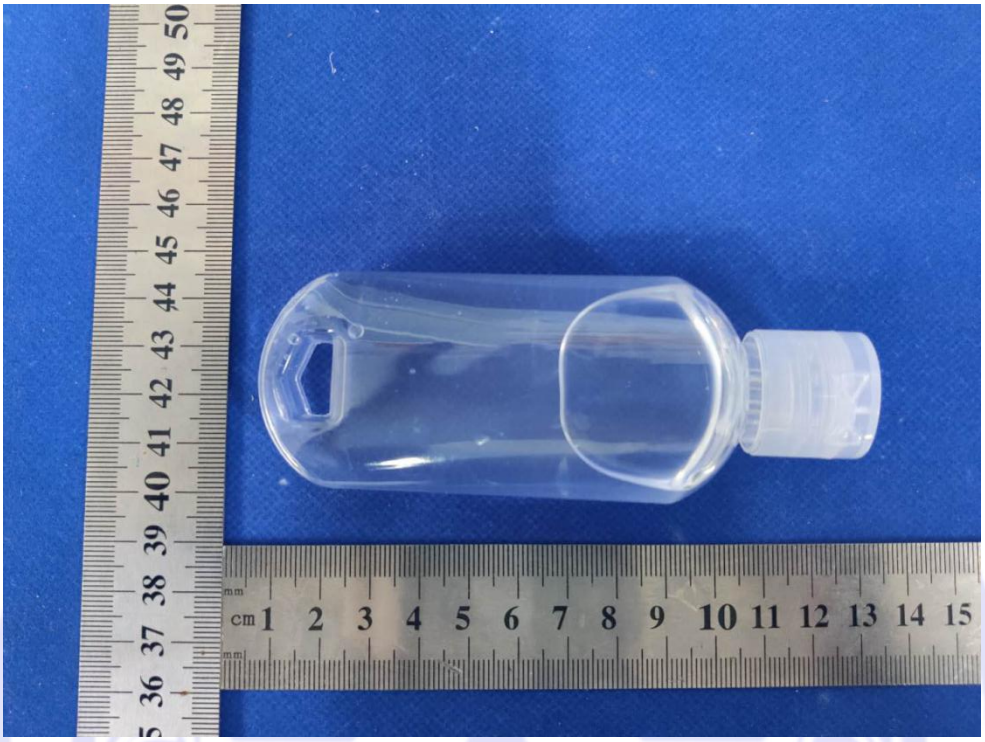

Photo 1 Overall view

--- End of report---