

Test Report

No.: NGBHL23005833101_1

Date: Dec 22, 2023

Page 1 of 5

Client Name: OUI LAB INC

Client Address: 15362 VALLEY BLVD CITY OF INDUSTRY CA 91746 UNITED STATES

Sample Description: MEDICAL GRADE SILICONE PELVIC FLOOR MUSCLE DILATOR

Style No.: INT-VW0005

Item No.: INT-VW0005

Client Ref. Information: INT-VW0011

The above sample(s) and information were provided by the client.

THIS REPORT IS TO SUPERSEDE TEST REPORT NO.NGBHL23005833101, DATE: Dec 19, 2023.

SGS No.: NBHL2312023037MD

Sample Receiving Date: Dec 07, 2023

Testing Period: Dec 07, 2023 ~ Dec 19, 2023

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

Testing Performed: Follow selected test(s) as requested by client.

	Test Requirement	Conclusion
1	Migration of certain elements	Pass
2	Bisphenol A	Pass

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch

Arnie Zeng

Arnie_Zeng
Approved Signatory

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SGS-CSTC Standards Technical Services Co., Ltd.
Ningbo Branch Chemical Laboratory

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Test Result(s):

Test Part Description:

SN ID	Sample No.	SGS Sample ID	Description
SN1	A1	NGB23-0058331-0001.C001	Purple silicone rubber body

Remarks:

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

Migration of certain elements

Test Method: With reference to EN 71-3:2019+A1:2021, analysis was performed by ICP-OES, IC-UV or LC-ICP-MS.

Test Item(s)	Limit	Unit(s)	MDL	A1
Soluble Lead(Pb)	ND	mg/kg	5	ND
Soluble Antimony(Sb)	ND	mg/kg	10	ND
Soluble Arsenic(As)	ND	mg/kg	10	ND
Soluble Barium(Ba)	ND	mg/kg	50	ND
Soluble Cadmium(Cd)	ND	mg/kg	5	ND
Soluble Chromium(III)(CrIII)	ND	mg/kg	5	ND
Soluble Chromium(VI)(Cr VI)	ND	mg/kg	0.025	ND
Soluble Mercury(Hg)	ND	mg/kg	10	ND
Soluble Selenium(Se)	ND	mg/kg	10	ND
Soluble Boron(B)	ND	mg/kg	50	ND
Soluble Cobalt(Co)	ND	mg/kg	10	ND
Soluble Manganese(Mn)	ND	mg/kg	50	ND
Soluble Strontium(Sr)	ND	mg/kg	50	ND
Soluble Zinc(Zn)	ND	mg/kg	50	ND
Soluble Copper(Cu)	ND	mg/kg	50	ND
Soluble Aluminum(Al)	ND	mg/kg	50	ND
Soluble Nickel(Ni)	ND	mg/kg	10	ND
Soluble Tin(Sn)	ND	mg/kg	3	ND
Soluble Organic Tin*	ND	mg/kg	-	ND
Conclusion				Pass

Notes:

- (1) According to Chapter of 10.1.2 of EN 71-3:2019+A1:2021, Chromium (III) is calculated by the following formula:
Soluble Chromium (III) = Soluble Total Chromium - Soluble Chromium (VI)
- (2) *Confirmation test of soluble organic tin is not required in case of soluble tin, after conversion, does not exceed the soluble organic tin requirement as specified in EN 71-3:2019+A1:2021.
- (3) The maximum permissible limit is quoted from the client requirement.

Bisphenol A

Test Method: With reference to EN 71-10:2005 followed by analysis with reference to EN 71-11:2005.



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No.: NGBHL23005833101_1

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Page 3 of 5

Test Item(s)	CAS No.	Limit	Unit(s)	MDL	A1
Bisphenol A	80-05-7	ND	mg/L	0.01	ND
Conclusion					Pass

Notes:

- (1) The test was subcontracted to SGS Shanghai chemical lab.
- (2) The maximum permissible limit is quoted from the client requirement.

This report updated Test requirement.

Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule (w=0) stated in ILAC-G8:09/2019.



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Sample Photo:



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