

Test Report

No. NGBHG2300189101

Date: 13 Mar 2023

Page 1 of 5

Client Name : HANGZHOU DARLLY FILTRATION EQUIPMENT CO,LTD

Client Address : NO. 1, BEISHAN NORTH ROAD, XINDENG TOWN, FUYANG DISTRICT, HANGZHOU, ZHEJIANG PROVINCE, 311404

Sample Name : PES PLEATED FILTER CARTRIDGE
 Item No. : NOT PROVIDED
 Manufacturer : HANGZHOU DARLLY FILTRATION EQUIPMENT CO,LTD
 Style No. : NOT PROVIDED
 The above sample(s) and information were provided by the client.

SGS Job No. : NBHL2303002918CW - NB
 Date of Sample Received : 01 Mar 2023
 Testing Period : 01 Mar 2023 - 13 Mar 2023
 Test Requested : Selected test(s) as requested by the client.
 Test Method(s) : Please refer to next page(s).
 Test Result(s) : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
US FDA 21 CFR 177.2600- Total Extractives	PASS
US FDA 21 CFR 177.2440- Chloroform-soluble extractives	PASS
US FDA 21 CFR 177.1520-Extractable fraction	PASS
US FDA 21 CFR 177.1520-Soluble fraction in Xylene	PASS
US FDA 21 CFR 177.1520-Density at 23°C	PASS

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

Pinky Wu

Pinky Wu
 Approved Signatory

scan to see the report



NGBHG2300189101



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

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Page 2 of 5

Test Result(s) :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	NGB23-001891.001	White plastic film	PP COPOLYMER
SN2	NGB23-001891.002	White plastic film	PES
SN3	NGB23-001891.003	Red brown silicone rubber ring	SILICONE RUBBER

US FDA 21 CFR 177.2600- Total Extractives

Test Method : With reference to US FDA 21 CFR 177.2600.

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 003 Total Extractives
Distilled Water	7.0hr(s)	Reflux temperature	20mg/inch ²	<0.5mg/inch ²
Succeeding Extraction	2.0hr(s)	Reflux temperature	1mg/inch ²	<0.5mg/inch ²
n-Hexane	7.0hr(s)	Reflux temperature	175mg/inch ²	10.2mg/inch ²
Succeeding Extraction	2.0hr(s)	Reflux temperature	4mg/inch ²	<0.5mg/inch ²

US FDA 21 CFR 177.2440- Chloroform-soluble extractives

Test Method : With reference to US FDA 21 CFR 177.2440

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 002 Net chloroform-soluble extractives
3% acetic acid	2.0hr(s)	refluxing temperature	0.02mg/inch ²	<0.01mg/inch ²
50% ethanol	2.0hr(s)	refluxing temperature	0.02mg/inch ²	<0.01mg/inch ²
n-Heptane	2.0hr(s)	refluxing temperature	0.02mg/inch ²	<0.01mg/inch ²
Distilled Water	2.0hr(s)	refluxing temperature	0.02mg/inch ²	<0.01mg/inch ²



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Page 3 of 5

US FDA 21 CFR 177.1520-Extractable fraction

Test Method : With reference to US FDA 21 CFR 177.1520 (d)(3)(ii).

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Extractable fraction</u>
n-hexane	2hr(s)	50°C	5.5% (w/w)	0.8% (w/w)

US FDA 21 CFR 177.1520-Soluble fraction in Xylene

Test Method : With reference to US FDA 21 CFR 177.1520(d)(4)(ii).

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Soluble fraction in Xylene	30	% (w/w)	0.5	4.2

US FDA 21 CFR 177.1520-Density at 23°C

Test Method : With reference to US FDA 21 CFR 177.1520d(1).

<u>Test Item(s)</u>	<u>Limit</u>	<u>001</u>
Density at 23°C, g/ cm ³	0.85-1.00	0.914

Remark:

- (1) g/cm³ = gram per cubic centimeter
- (2) %(w/w) = percentage of weight by weight
- (3) °C = degree Celsius
- (4) hr = hour
- (5) < = less than
- (6) MDL = Method Detection Limit
- (7) ND = Not Detected (< MDL)
- (8) mg/inch² = milligram per square inch

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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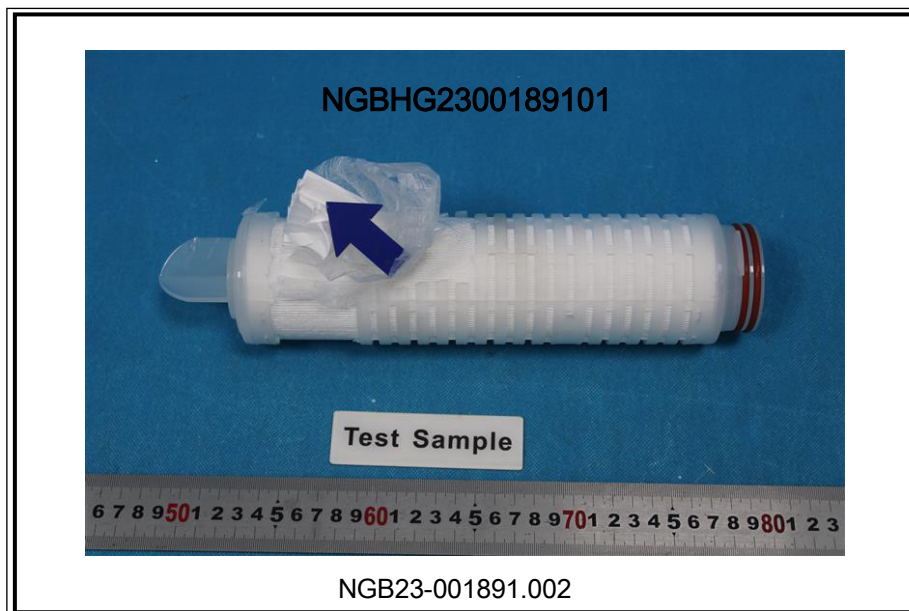
Test Report

No. NGBHG2300189101

Date: 13 Mar 2023

Page 4 of 5

Sample photo:



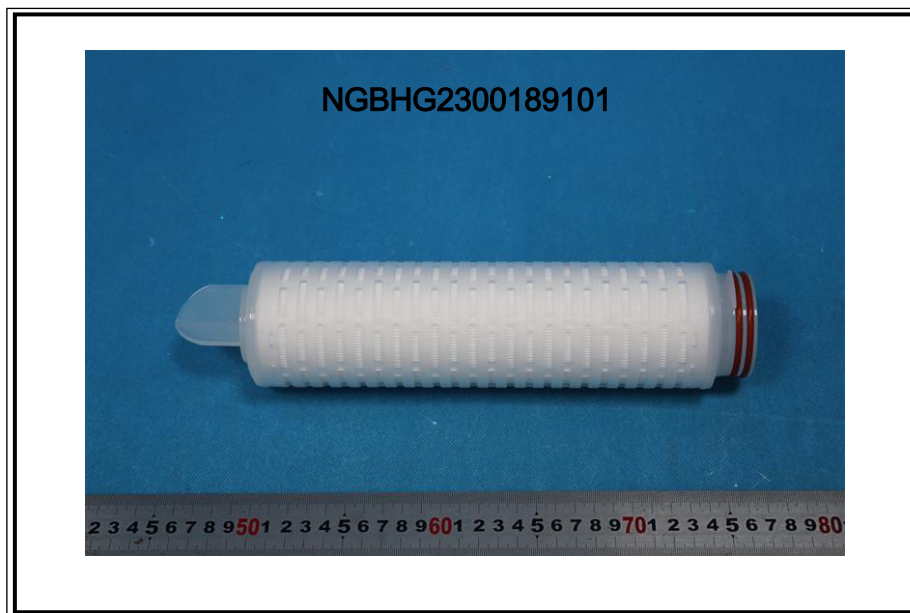
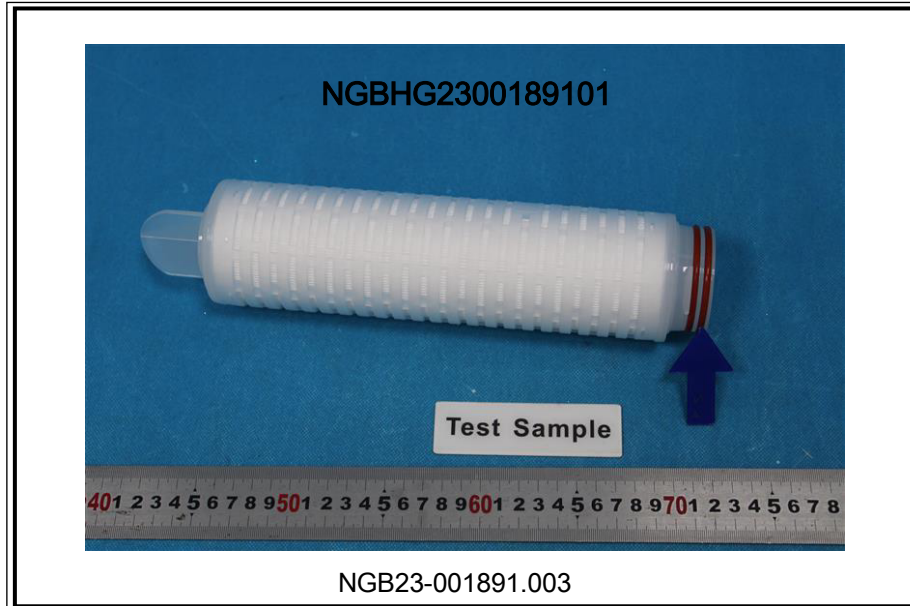
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