
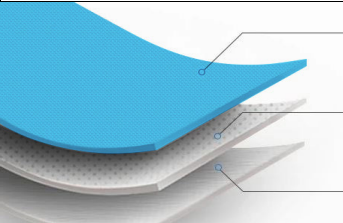




Ficha Descriptiva Mascarilla Tres Pliegos Tipo IIR (Norma Europea)

Nombre Producto	Mascarilla Médica Tipo IIR "Quirúrgico"	
Descripción	Mascarilla facial descartable plana, cubre la nariz y la boca del usuario y provee una barrera para fluidos y materiales particulados.	
Aspecto	Mascarilla inodora, plana, con tres pliegues. Posee un sellado por ultrasonido resistente y alambre sobre el tabique de la nariz para poder amoldarlo a su forma. Libre de sustancias tóxicas o irritantes por contacto o inhalación. No desprende partículas.	
Sujeción	Facilidad de sujeción hacia la cara por medio de dos bandas elasticadas. Permite colocar la mascarilla de manera fácil y rápido, reduciendo la manipulación durante su postura.	
	Se recomienda tener el menor contacto posible con la mascarilla para evitar contaminación.	
Imagen		
Color	Celeste	
Talla Estandar	Si, para todos los rostros, sin necesidad de amarre, sujeción por elástico.	
Tamaño	Tamaño (+ - 0,5 cm) 17,5 x 9,5 cm	
No estéril (aséptico)	Si	
Rotulado	Si	
Envase y/o Embalaje	Pack 3, 5 y 10 unidades. Display 25 o 50 unidades.	
Peso capas (+/- 2 gr.)	Capa externa 25 gr./m2, Capa interna 25 gr./m2, Capa intermedia 25 gr./m2	
Rol y Materialidad de Cada Capa		Externa: Tela no tejida, respirable, bloquea bacterias y filtra gotas de agua (hidrofóbica), no humeda.
		Intermedia: Tela no tejida tipo meltblown que actúa como filtro de partículas pequeñas.
		Interna: Tela no tejida, para bloquear paso de bacterias. Respirable y confortable como capa interior.
Eficacia de Filtración Bacteriana (BFE)	NORMATIVA EUROPEA EN 14683:2019+AC:2019 SGS-CSTC Standards Technical Services Shanghai Co., Ltd Testing Center	≥ 99%
Presión Diferencial (Respirabilidad)		38,2 (Pa/cm2)
Resistencia a Salpicaduras		120mmHg (16,0kpa)
Limpieza Microbiana		9,54 (cfu/g)

ANEXO NORMA EUROPEA: Requisitos de Funcionamiento de las Mascarillas Quirúrgicas

Norma: EN 14683:2019+AC:2019

Ensayo	Tipo I	Tipo II	Tipo IIR
Eficacia de filtración bacteriana (BFE) <i>Norma UNE-EN 14683: 2019</i>	≥ 95%	≥ 98%	≥ 98%
Respirabilidad o Presión Diferencial (Pa/cm2) <i>Norma UNE-EN 14683: 2019</i>	< 40	< 40	< 60
Presión de Resistencia a las Salpicaduras (kPa) <i>Norma UNE-EN 14683: 2019 ISO 22609 / ASTM F1862</i>	No requerido	No requerido	≥ 16
Limpieza Microbiana o Carga Biológica (ufc/g) <i>Norma UNE-EN 14683: 2019 Norma EN ISO 11737-1: 2018</i>	≤ 30	≤ 30	≤ 30

Test Report

SL52035273962001TX

Date: August 04, 2020

Page 1 of 3

COMERCIAL OLICORP PERU SAC
CANTUARIAS 160 OFICINA 603, MIRAFLORES

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

Sample Description : (A)Mascarilla descartable de 3 pliegues//Disposable mask with 3 folds
Production date: Jul 17, 2020(07/17/2020)

Composition : (A)Spunbond 25 grs/m2- Meltblown 25 grs/m2- Spunbond 25 grs/m2
Sample Color : (A)Blanco/White
Style No. : Deysa
Lot No. : 0050
Manufacturer : DEYSA CHILE
Supplier : DEYSA CHILE

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jul 23, 2020

Testing Period : Jul 23, 2020 - Aug 04, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Helen Xuan

Helen Xuan (Authorized Signatory)



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Test Report

SL52035273962001TX

Date: August 04, 2020

Page 2 of 3

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**Clause 5.2 Performance Requirement****Clause 5.2.2 Bacterial Filtration Efficiency (BFE)**

(EN 14683:2019+AC:2019 Annex B)

Sample: A
 Test Side : Inside
 Test Area : Approximately 60 cm²
 Flow Rate : 28.3 L/min
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : ~171mm x 152mm
 Positive Control Average : 2127.5 CFU
 Negative Monitor Count : < 1 CFU
 Mean Particle Size : 3.0 ±0.3µm
 Test bacteria : Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.8%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:

- 1) Performance Requirement: Type I ≥ 95%, Type II ≥ 98%, Type IIR ≥ 98%
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL (Acceptable Quality Level) of 4%.



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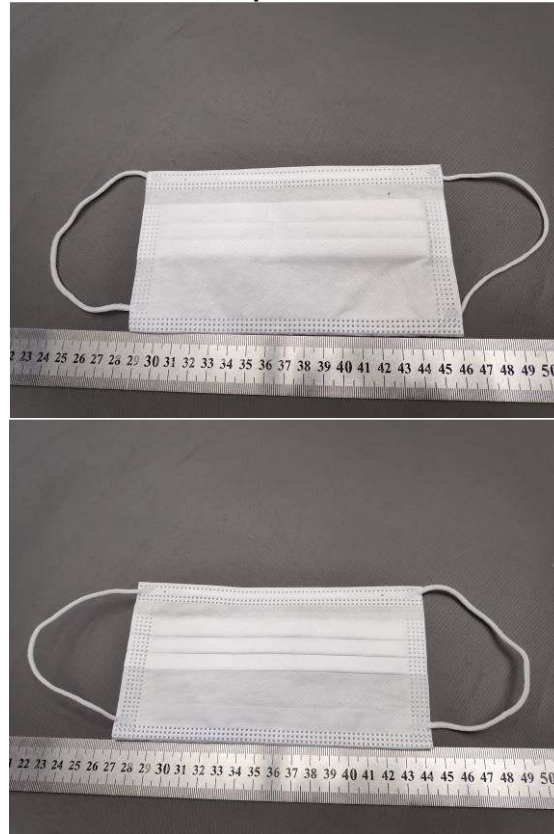
Test Report

SL52035273962001TX

Date: August 04, 2020

Page 3 of 3

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

Test Report **SL52035284847501TX**
COMERCIAL OLICORP PERU SAC
CANTUARIAS 160 OFICINA 603, MIRAFLORES

Date: August 21, 2020

Page 1 of 5

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

Sample Description : (A)Mascarilla Descartable de 3 Pliegues // Disposable Mask with 3 Folds

Composition : (A)Spunbond 25 grs/m2- Meltblown 25 grs/m2- Spunbond 25 grs/m2

Sample Color : (A)Blanco/ White

Style No. : Deysa

Lot No. : 0050

Manufacturer : Deysa Chile

Supplier : Deysa Chile

Other Info. : Production date: Jul 17,2020 (07/17/2020)


Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Aug 03, 2020

Testing Period : Aug 03, 2020 - Aug 21, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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



Sara Guo (Account Executive)



Dongjing Liu (Authorized Signatory)



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Test Result

Resistance to Penetration by Synthetic Blood
(ASTM F1862/F1862M-2017)

Sample: A

Test Blood Pressure : Level 1 Barrier-80mmHg(10.6kpa)

Test volume of synthetic blood : 2 mL

Pre-Conditioning : Minimum of 4 hours at 21±5°C (70±10°F) and 85±5% R.H.

Distance of the mask to the tip of cannula : 30.5cm (12.0 in.)

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	Seen	Fail
4	None Seen	Pass	20	None Seen	Pass
5	Seen	Fail	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:			30		
Overall result:			Acceptable		

Remark:

- 1) Test was conducted within 1min after removal from conditioning chamber.
- 2) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.



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Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Test Area : 4.9 cm²

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm ²)	The average value for each test specimen (Pa/cm ²)
1	1-1	32.8	38
	1-2	39.4	
	1-3	38.2	
	1-4	39.6	
	1-5	37.9	
2	2-1	39.2	38
	2-2	36.1	
	2-3	39.3	
	2-4	38.2	
	2-5	39.4	
3	3-1	39.4	38
	3-2	34.5	
	3-3	38.7	
	3-4	39.1	
	3-5	38.2	
4	4-1	33.4	38
	4-2	39.1	
	4-3	38.7	
	4-4	39.6	
	4-5	38.5	
5	5-1	36.6	39
	5-2	38.9	
	5-3	39.6	
	5-4	37.8	
	5-5	39.7	



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Specimen No.	Test Area No.	Different Pressure for each tested area (mm H ₂ O/cm ²)	The average value for each test specimen (mm H ₂ O/cm ²)
1	1-1	3.28	3.8
	1-2	3.94	
	1-3	3.82	
	1-4	3.96	
	1-5	3.79	
2	2-1	3.92	3.8
	2-2	3.61	
	2-3	3.93	
	2-4	3.82	
	2-5	3.94	
3	3-1	3.94	3.8
	3-2	3.45	
	3-3	3.87	
	3-4	3.91	
	3-5	3.82	
4	4-1	3.34	3.8
	4-2	3.91	
	4-3	3.87	
	4-4	3.96	
	4-5	3.85	
5	5-1	3.66	3.9
	5-2	3.89	
	5-3	3.96	
	5-4	3.78	
	5-5	3.97	

Remark:

The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

Microbial Cleanliness

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (cfu/mask)	Total Bioburden, (cfu/g)
1#	2.95	27	9.15
2#	2.92	12	4.11
3#	2.93	27	9.22
4#	2.99	30	10.03
5#	2.96	45	15.20

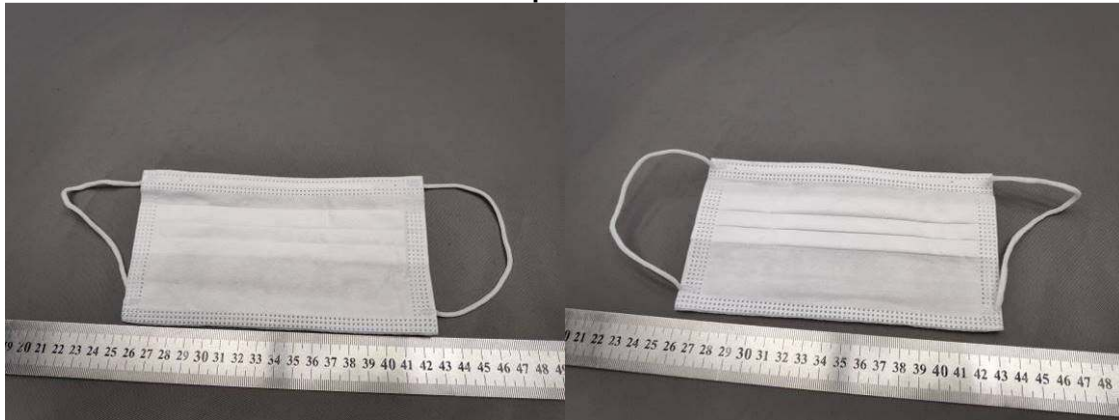


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Sample Photo



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Test Report

SL52035298811801TX

Date: September 29,2020

Page 1 of 3

COMERCIAL OLICORP PERU SAC
CANTUARIAS 160 OFICINA 603, MIRAFLORES

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

Sample Description : (A)Mascarilla Triple Pliego

Composition : (A)Tela no tejida Spunbond 25 grs/m2 - Meltblown 25 grs/m2 - Spunbond 25 grs/m22

Sample Color : (A)Blanco/White

Style No. : Triple Pliego - Triple capa

Lot No. : 0051

Manufacturer : Deysa Chile

Supplier : Deysa Chile

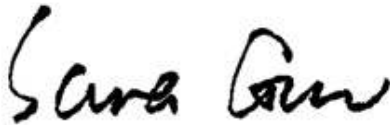
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Sep 22, 2020

Testing Period : Sep 22, 2020 - Sep 29, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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



Sara Guo (Account Executive)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**Clause 5.2 Performance Requirement****Clause 5.2.4 Splash Resistance**

(ISO 22609 :2004)

Sample: A

Test Blood Pressure : 16.0kPa

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	Seen	Fail	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		31			
Overall result:		Acceptable			

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Test was conducted within 60s after removal from conditioning chamber.
- 3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.



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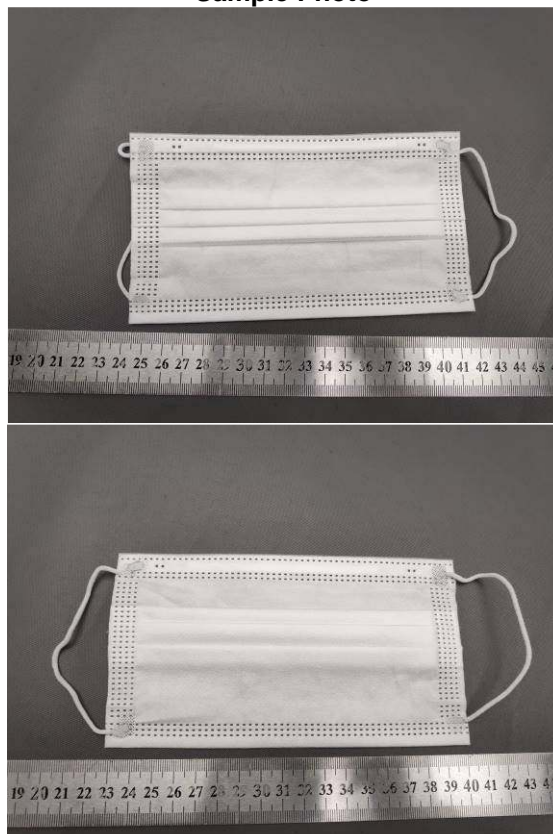
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Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



CERTIFICADO



Certifica que a empresa

MOTECH DO BRASIL INDÚSTRIA DE PLÁSTICOS LTDA.

Rod. BR 116 S/N, Quadras I e II - Distrito Industrial dos Imborés
45089-340 - Vitória da Conquista - BA
Brasil

implementou e mantém um
Sistema de Gestão da Qualidade.

Escopo:
Fabricação e comercialização de embalagens plásticas flexíveis, TNT laminado, filmes
higiênicos e TNT - tecido não tecido (nonwoven)

Através de uma auditoria, documentada em um relatório, foi comprovado
que o sistema de gestão cumpre os requisitos da seguinte norma:

ISO 9001 : 2015

Número do certificado	464546 QM15
Válido a partir de	02-08-2018
Válido até	01-08-2021
Data da certificação	02-08-2018

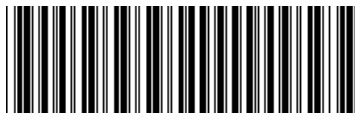


DQS do Brasil Ltda.

Dezée Mineiro
Diretora Executiva

TEST REPORT

(Electronic version)



No:200048

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: FRBB-1319

ISSUE DATE 签发日期:2020-03-26

客户认定信息 APPLICANT PROVIDED SAMPLE DESCRIPTION:

熔喷布MELT BLOWN FABRIC 30cm×200cm

生产单位 MANUFACTURE'S NAME:

DATE RECEIVED/DATE TEST STARTED: 2020-03-21

样品受理/测试开始日期: 2020-03-21

CONCLUSION 结论:

BACTERIAL FILTRATION EFFICIENCY

M

细菌过滤效率

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER

NaCl颗粒物过滤效率

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT

"---" -NO COMMENT

备注: "M" -符合要求 "F" -不符合标准要求

"---" -此项目不判定

REMARK:

TEST MATERIAL, FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER WAS TESTED BY GB 2626-2006, AND BACTERIAL FILTRATION EFFICIENCY WAS TESTED AND JUDGED BY YY/T 0969-2013 AS PER CLIENT'S REQUIREMENT.

原材料测试, 客户要求NaCl颗粒物过滤效率按GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》检测, 细菌过滤效率按YY/T 0969-2013 《一次性使用医用口罩》检测和判定。

ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).

本报告中检验检测项目均在相应标准规定的环境条件下进行(有注明的除外)。

COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.

复印件、副本未重新加盖报告书确认章无效。

THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R. CHINA.

本报告检验检测地址为广州市番禺区珠江路1号。

APPROVED BY(签发):

马楠 工程师

Nan Ma ENGINEER



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BACTERIAL FILTRATION EFFICIENCY(%)

细菌过滤效率(%)

(YY 0469-2011 ANNEX B 附录B, TEST BACTERIA 测试菌种: STAPHYLOCOCCUS AUREUS ATCC 6538
金黄色葡萄球菌ATCC 6538, TEST AREA 测试面积: 40cm^2 , FLOW RATE 气体流速: 28.3L/min ,
MEAN PARTICLE SIZE 平均颗粒直径: $3.0\mu\text{m}$, RESULT OF THE POSITIVE CONTROL 阳性质控值:
 1.9×10^3 CFU, RESULT OF THE NEGATIVE CONTROL 阴性质控值: $<1\text{CFU}$)

		REQUIREMENT 要求
BFE ₁	99.9	≥ 95
BFE ₂	99.8	(YY/T 0969-2013)
BFE ₃	99.6	

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER

NaCl颗粒物过滤效率

(GB 2626-2006 6.3, AIR FLOW 空气流量: 85L/min , AEROSOL 气溶胶颗粒: NaCl, AEROSOL
CONCENTRATION 气溶胶浓度: 15mg/m^3 , TEMP 温度: 23.3°C , RH 相对湿度: 36.2%)

FILTRATION EFFICIENCY 过滤效率(%):

UNTREATED SAMPLE 未处理样品

1# 80.5
2# 79.6
3# 77.7
4# 81.4
5# 82.5
6# 82.1
7# 78.6
8# 80.3
9# 82.1
10# 82.5

CONDITIONING TREATED 温湿度预处理后样品

1# 81.2
2# 79.6
3# 78.3
4# 78.2
5# 80.1

——本报告结束(End of Report)——

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