Cambridge
materials testing limited

6991 Millcreek Drive, Unit 13
Mississauga, Ontario L5N 6B9
Tel: (905) 812-3856 Fax: (905) 812-3866
www.cambridgematerials.com

Report For:	Dorma Lab 1055 Beaver Hall, Suite 400 Montreal, Quebec H2Z 1S5 Phone: 514 833 6584 855 218 5186 (Work) Email: rene.caissie@mac.com	Laboratory #: Report Date: Received Date:	841243-20 August 10, 2020 July 27, 2020
Attention:	Dr. Rene Caissie		
Specimen:	#1: Filtration Media		

TEST REPORT

One specimen, consisting of filtration media, was submitted to be tested for bacterial filtration efficiency to determine acceptability for barrier classification under ASTM F2100-19 requirements.

Note: This report ONLY contains results for one of the five requirements as per ASTM F2100-19. Unless all the tests are performed, final overall performance level cannot be achieved for the submitted sample.

Medical Face Mask Material Requirements

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier	Summary Results
Bacterial Filtration Efficiency, %	≥95	≥98	≥98	Pass Any Level
Differential Pressure, mm H_2O/cm^2	<5.0	<6.0	<6.0	Not Performed
Sub-Micron Particulate Filtration Efficiency at 0.1 micron, %	≥95	≥98	≥98	Not Performed
Synthetic Blood Penetration minimum pressure in mmHg for pass result	80	120	160	Not Performed
Flame Spread	Class 1	Class 1	Class 1	Not Performed
OVERALL PERFORMANCE LEVEL	Incomplete			

Cambridge Materials Testing Limited

Per _____
Authorized By Stephen Brown

Per _____
Technician, Derek Wild

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Laboratory # 841243-20
Dorma Lab

BACTERIA FILTRATION EFFICIENCY (BFE)
Testing performed by GAP EnviroMicrobial Services Ltd., 1020 Hargrieve Road, Unit 14, London, Ontario, Canada, N6E 1P5

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101-19 to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts recovered downstream. A suspension of *S. aureus* was aerosolized using a nebulizer and delivered to the test article at a constant rate with a target delivery rate of $1.7 \times 10^3 - 3.0 \times 10^3$ colony forming units (CFU) per test article with a mean particle size of 3.0 ± 0.3 µm. The aerosolized suspension was drawn through the test article which was clamped in a six stage Andersen air sampler, at a constant flow rate of 28.3 liters per minute (LPM), for collection on bacteriological agar plates.

Challenge Microbe: *Staphylococcus aureus* ATCC 6538
Test Side: Side undetermined, flat sheet
Area Tested: ~38.5 cm^2
Flow Rate: 28.3 LPM
Test Article Conditioning: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Challenge Level: 5.203×10^3 CFU
Mean Particle Size: 2.95 µm
Note: A challenge level of $>3.0 \times 10^3$ CFU was accepted, as control plates remained in a countable range and particle size remained within limits for all controls.

Requirements ASTM F2100-19:
Bacteria filtration efficiency (%)
Level 1 Barrier: ≥95
Level 2 Barrier: ≥98
Level 3 Barrier: ≥98

RESULTS

Specimen #	Total CFU Recovered	Percent BFE (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	<1	>99.98	Pass	PASS Any Level
1-2	<1	>99.98	Pass	
1-3	<1	>99.98	Pass	
1-4	<1	>99.98	Pass	
1-5	<1	>99.98	Pass	

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Challenge Level
T = Total CFU recovered downstream of test article

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ANALYSIS REPORT
SCC Accreditation No.: 40‡

Mr. René Caissie
Dorma Lab

Date: August 18, 2020
Report: 5827-001T-4B-en

IDENTIFICATION: Filter for BRP mask: SP Teflon
Received: April 21, 2020

STANDARD:

TEST: Test Method for Filtration of 0.3 micron NaCl particles by Materials Used in Medical Face Masks GCTTG 154-20‡

TEST CONDITIONS: The test was subcontracted to another laboratory;
Conditioning atmosphere: 21±5°C, 85±5% R.H. for a minimum of 4 hours;
Air flow (L/min): 85
Date of test: April 23 2020

RESULTS:	Individual Data					Avg.	S.D.	% CV
Resistance (mm H2O):	91.8	146	123	90.1	97.3	**107.0**	18.6	**17.4**
	114	114	84.3	100	92.7			
	96.1	149	128	93.0	100			
	117	118	86.9	105	95.0			
Resistance (Pa):	900	1430	1210	884	954	**1 049**	183	**17.4**
	1120	1120	827	982	909			
	942	1460	1250	912	985			
	1150	1160	852	1010	932			
Penetration percentage (%):	0.0570	0.00900	0.0310	0.0400	0.0290	**0.0320**	0.0149	**46.8**
	0.0400	0.0220	0.0290	0.0260	0.0250			
	0.0460	0.00100	0.0200	0.0590	0.0400			
	0.0420	0.0170	0.0490	0.0320	0.0250			
Filtration efficiency (%):	99.9	100	100	100	100	**100**	0	**0.0**
	100	100	100	100	100			
	100	100	100	99.9	100			
	100	100	100	100	100			

Prepared by:
Katrine Tourchet,
Technician

Approved by:
Alejandro Manponé, Eng., Ph.D.
Project Leader

Date: August 18, 2020

***For any information concerning this report, please contact Alejandro Manponé ***

GroupeCTTGroup

ANALYSIS REPORT
SCC Accreditation No.: 40[;

Mr. René Cossie
Dorma Lab

Date: August 14, 2020
Report: 5827-001T-1A-en

IDENTIFICATION:	3D Printed Respirators with removable cartridge. Cartridge with pleated filtering media Received: August 10, 2020
STANDARD:	
TEST:	Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) — ASTM F1862/F1862M-17[;
TEST CONDITIONS:	Conditioning atmosphere: 21±5°C, 85±5% R.H.; Testing atmosphere (<1 minute): 23.5°C ; 74% H.R. ; Distance of the mask from the cannula: 30.5cm Volume of fluid impacting the masks: 2.0±1ml Blood penetration detection: NAKED_EYE Number of specimens tested: 32 Date of test: August 12,2020

RESULTS:	Individual Data				
Stream velocity (cm/s):	650				
Corresponding blood pressure (mmHg):	160				
Blood penetration (pass/fail):	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass
	Pass	Pass			

Prepared by:
Patrick Dubois,
Technician

Approved by:
Alejandro Maupomé, Eng., Ph.D.
Project Leader

Date: August 14, 2020

For any information concerning this report, please contact Alejandro Maupomé.

The reports are identified by an alphanumeric code, the letter preceding "-en" refers to the revision number, omitted in ascending order. The electronic copy sent by CTT Group is the official report. The reported identification is based on what was observed on the received sample and/or information provided by the customer. The samples in relation to this report are retained for a period of 30 days following transmission of the report. The above reported results refer exclusively to the samples submitted for evaluation. This analysis report cannot be partly used or reproduced, unless in whole, without CTT Group prior written consent. [The ISO/IEC 17025 Scope of Accreditation of CTT Group is available at www.gctg.com. In this report, the tests which number is followed by the symbol [are not covered by the accreditation. For customer's complete address, please refer to the email.

KRAIBURG TPE GmbH & Co. KG
Friedrich-Schmidt-Str. 2
84478 Waldkraiburg
Germany
USt-IdNr.: DE249813021
Tel.: +49 (0) 8638 9810-0
Tel.: +49 (0) 8638 9810-310
info@kraiburg-tpe.com
www.kraiburg-tpe.com
Handelsregister Traunstein
HRA 9269

MI Integration
3100 Boulevard Industriel
Sherbrooke, Quebec J1L 1V8
Canada

Statement reg. biocompatibility testing according to "most extreme compound approach" for THERMOLAST®M

Dear Sir or Madam,

All grades, which include the same THERMOLAST® M series suffix as e.g. "MED", share the same formulation. The difference in durometer between e.g. **TM4MED** and **TM9MED**, are created by adjusting the dosage of one hardness controlling ingredient. In this case, it is a medical grade PP. The highest content of this ingredient will be found in **TM9MED**.

Consequently, the grades which have the highest durometer are considered as the "most extreme compound" of each compound series. As such, test results are representative for all grades of this compound series with lower durometers.

All tests for e.g. ISO 10993 or USP class VI conducted for **TM9MED**, yielded passing results. Therefore, the softer compound of this series, such as e.g. **TM4MED** is also covered by these test results.
Please note, Drug Master file # 22979 is assigned for the MED compound series and is valid for all hardness ranges, including **TM4MED**.

Thus, we are convinced our material, **TM4MED** will pass further biocompatibility tests, including but not limited to: ISO 10993-5 (passed, up to date), 10993-10 and 10993-11.

Medizinprodukte Berater
Oliver Kluge
Market Segment Manager Medical Applications
KRAIBURG TPE GmbH & Co. KG

PHG
KRAIBURG TPE Verwaltungs GmbH
Sitz Waldkraiburg
Handelsregister Traunstein
HRB 17379
GF: Franz Hollweck

Health Canada / Santé Canada

Id: 155025

Licence Number **14230** Numéro de la licence

Medical Device Establishment Licence

Licence d'établissement pour les instruments médicaux

DORMA DBA DORMA SOINS DU SOMMEIL

1055 BEAVER HALL HILL
SUITE 400
MONTREAL, QUEBEC
CANADA
H2Z 1S5

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Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	Yes / Oui	Yes / Oui
Class II / Classe II	No / Non	Yes / Oui	
Class III / Classe III	No / Non	Yes / Oui	
Class IV / Classe IV	No / Non	No / Non	

Attestation made : **Attestations faites :**

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre une procédure écrite concernant:
• distribution records	[Y]	• les registres de distribution
• complaint handling	[Y]	• les plaintes
• recalls	[Y]	• les rappels
• mandatory problem reporting	[Y]	• rapports d'incident obligatoires
• handling, storage, delivery	[Y]	• la manutention, le stockage, la livraison
• installation	[Y]	• l'installation,
• corrective action	[Y]	• les mesures correctives
• servicing	[Y]	• l'entretien

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Issue Date, date de délivrance: 2020-06-30

Minister of Health / Ministre de la santé	Countersigned: Director, Medical Devices Compliance Program or delegated authority / Contresigné par: Directrice, Programme de la conformité des matériels médicaux ou autorité déléguée
	Anik Michelle Chartrand

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.
Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.

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