Consultancy and Laboratory Services for Biomedical Quality

DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

REPORT N. 3037-20 Rev.00

Customer: CMT Equipment Ltd
Trident Works, Mulberry Way, - Belvedere, DA 17 6AN - UK

TIME SCHEDULE

Acceptance N.:	20-2837
Samples receiving date:	11/05/2020
Start test date:	13/05/2020
End test date:	13/05/2020
Coronati Consulting Operator:	Dr. F. Bergonzini

TEST LABORATORY
Coronati Consulting srl Via L. Gavioli, 3 I-41037 Mirandola (MO) Certified ISO 9001/ ISO 13485

REFERENCE DOCUMENTS
UNI EN 14683:2019 "Medical face masks - Requirements and test methods" - Annex C

TEST SAMPLE IDENTIFICATION

Name (1÷5):	Type IIR Medical Mask
Sample Typology:	Surgical Type IIR 3-Layer Mask Non-Sterile
Composition:	Non-Woven - Technical sheet in attach For additional information see Annex 01
Quantity tested:	5
Code (REF):	SM120
Batch:	200501
Manufacturing date:	05/2020
Expiry date:	05/2025
Sterilization Method:	UVGI
Sterilization Batch:	NOT PROVIDED
Sterilization Date:	NOT PROVIDED
Sterilization Unit:	NOT PROVIDED

The information concerning the test sample were provided by the Customer. All data related to the test sample are under the responsibility of the Customer and have not been verified by the test laboratory.

Issue Date	Rev.	Change Description	Prepared by: Dr. F. Bergonzini (Laboratory Technician)	Verifed and Approved by: Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
14/05/2020	00	First Issue		

This test report is digitally signed by Dr. Renzo Giovanni Coronati.
The digital signature has legal value according to Italian D. Lgs. 82/2005 and subsequent amendments.

The sampling is performed by the Customer. The test results are related only to the test samples as received.
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PROCEDURES
All procedures used during this study are recorded in the Laboratory Coronati Consulting s.r.l.

PURPOSE
The purpose of this procedure is to evaluate the suitability of the mask in meeting the breathability requirement as specified in the reference standard document. Determining the differential pressure between the two sides of the sample crossed by a constant and controlled air flow, this procedure allows you to evaluate whether this device has sufficient air permeability.

OPERATING METHODS (according to UNI EN 14683:2019 Annex C, par. C.4)
Each sample is placed in the holder and subjected to an 8 l/min air flow generated by a vacuum pump. The differential pressure on the tested area is read directly using a differential manometer. Tested areas number and location on mask are reported in the following figure 1.

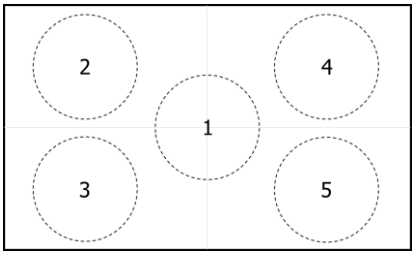

Figure 1

ACCEPTANCE CRITERIA (according to UNI EN 14683:2019 par. 5.2.7, table 1)

	Type I	Type II	Type IIR
Differential pressure	< 40 Pa/cm^2	< 40 Pa/cm^2	< 60 Pa/cm^2

RESULTS

	Differential Pressure (ΔP)				
	Flow rate: 8 L/min				
N° test area	Sample 1 (Pa/cm^2)	Sample 2 (Pa/cm^2)	Sample 3 (Pa/cm^2)	Sample 4 (Pa/cm^2)	Sample 5 (Pa/cm^2)
1	12,9	9,3	10,7	8,9	9,7
2	10,8	10,9	9,7	11,5	10,9
3	7,0	10,0	7,9	13,4	11,7
4	10,4	8,2	9,3	8,8	8,3
5	8,6	8,0	13,3	7,9	10,8
ΔP Average	9,9	9,3	10,2	10,1	10,3

ANNEXES
Annex 01: Sample Composition/Drawing Sample

----------End of Report----------

Consultancy and Laboratory Services for Biomedical Quality

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PP Meltblown nonwoven 25g/m2

Technical data sheet

Property:	Norm:	Unit:	Value:
Application			Face mask
Materiaal			Polypropylene
Fabric weight	NWSP 130.1	g/m2	25
Thickness	NWSP 120.6	mm	0,35
Bacterial Filtration Efficiency	EN 14683	%	≥ 98
Air permeability (200 Pa)	NWSP 070.1	l/m2/s	450
Initial pressure drop (0.05 m/s) (95 l/min)	NWSP 070.1	Pa	< 25
Initial efficiency NACL 3 (µm)		%	98
Product width		mm	175
Roll length		m	2500
Roll outer diameter		cm	60
Core inner diameter		mm	76
Roll weight		kgs	11
Rolls are packed in PE Film			

Date: March 10th 2020

This information is provided in good faith but Q-Nonwovens BV cannot guarantee its accuracy or completeness. The end user is advised to evaluate the product and use it only in compliance with all applicable laws and regulations. This is not a specification. Properties are given as typical values.

Thickness measured under relaxed conditions. May vary after packaging, storage and transport.

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Q-Tex PP spunbonded nonwoven 25g/m2 white

Technical Data Sheet

Physical properties:	Test method:	Unit:	Value:
Application			Face mask
Material			Polypropylene
Colour			white
Weight	EN 29073	g/m2	25
Tensile strength	EN 29073	N/5cm	50
Treksterkte CD	EN 29073	N/5cm	30
Rek MD	EN 29073	%	60
Rek CD	EN 29073	%	60

No warranties can be provided against any of our recommendations and values or claims regarding the applications of our products either used exclusively or in conjunction with other materials.

Date: 17.04.2020