Consultancy and Laboratory Services for Biomedical Quality

TOTAL MICROBIAL CONTAMINATION (Bioburden)

REPORT N. 3768-20 Rev. 00

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

TEST METHOD ISO 11737-1:2018 Annex B.2

TIME SCHEDULE	Acceptance N.:	20-3575
	Reception date:	01/06/2020
	Start test date:	03/06/2020
	End test date:	08/06/2020
	Operator:	Dr. L. Gavioli
TEST SAMPLE IDENTIFICATION	Name:	Type IIR Medical Mask
	Sample Typology:	Surgical Type IIR 3-Layer Mask Non-Sterile
	Composition:	Non-Woven – (For additional information see Annex 01)
	Quantity tested:	5
	Code (REF):	SM120
	LOT:	200502
	Manufacturing date:	05/2020
	Expiry date:	05/2025
	Sterilization Method:	UVGI

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. L. Gavioli (Laboratory Technician)	Verified and Approved by Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
08/06/2020	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.

TEST LABORATORY: Coronati Consulting srl Via L. Gavioli, 3 I-41037 Mirandola (MO) Italy Tel.+39 0535611533 Fax +390535410441
E-mail: info@coronaticonsulting.it Web: www.coronaticonsulting.it

LAB N° 1496 L

PROCEDURES
All procedures used during this study are recorded in the Laboratory Coronati Consulting s.r.l.

OPERATING METHODS
The test was performed in aseptic conditions under ISO Class 5 laminar flow hood. Each sample was submitted to the washing according to the standard ISO 11737-1:2018 Annex B.2 under particular conditions determined during validation phase for that kind of products or family of products. After the filtration of washing solution, the filters were incubated to one part on Petri dishes containing TSA (Tryptone Soya Agar) and incubated for 72h at 32,5 ± 2,5 °C suitable for bacteria investigation, and the other part on Petri dishes containing SDA (Sabouraud Dextrose Agar) and incubated for 5 days at 22,5 ± 2,5 °C suitable for yeasts and molds investigation. At the end of incubation, C.F.U. (Colony-Forming Units) were countered, considering Correction Factor determined during Recovery Validation Testing.
The Correction Factor below is derived from the report of Customer validation method n. 3768-20 Rev.00 dated 08/06/2020.

ACCEPTANCE CRITERIA
The tests are conformed when the results are not higher then limit 30 C.F.U./g (According to UNI EN 14683:2019 par.5.2.5).

RESULTS

Id.	Microbiological Contamination			Correction Factor	Bioburden (C.F.U./Mask)	Bioburden (C.F.U./g)	Acceptance Criteria (C.F.U./g)	Conformity Evaluation
	Bacteria (C.F.U./Mask)	Yeasts and Molds (C.F.U./Mask)	Total (C.F.U./Mask)					
1	48	12	60	1,3	78	22	≤ 30	PASS
2	12	8	20	1,3	26	8	≤ 30	PASS
3	18	0	18	1,3	23	7	≤ 30	PASS
4	56	4	60	1,3	78	23	≤ 30	PASS
5	26	6	32	1,3	42	12	≤ 30	PASS
(1) according to UNI EN 14683:2019 par.5.2.5								

DEVIATION
No deviation has been remarked during the study.

ANNEXES
Annex 01: Sample Composition/Drawing Sample provided by the Customer.

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

Coronati consulting lab

Consultancy and Laboratory Services for Biomedical Quality

Sample Composition/Drawing

Q-Nonwovens BV
Landbouwweg 22
3899 BE Zeewolde
The Netherlands

T +31 36 522 77 78
F +31 36 522 00 72
M +31 6 3839 62 33
E sales@qnw.nl

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

Coronati consulting lab

Consultancy and Laboratory Services for Biomedical Quality

Q-NONWOVENS

Q-Nonwovens BV
Landbouwweg 22
3899 BE Zeewolde
The Netherlands

T +31 36 522 77 78
F +31 36 522 00 72
M +31 6 3839 62 33
E sales@qnw.nl

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.