Consultancy and Laboratory Services for Biomedical Quality

SUMMARY TEST REPORT according to EN 14683

REPORT N. 6481-20 Rev. 00

Customer: Softcom OÜ
Turu 5B 48303 - Jõgeva - Estonia

TIME SCHEDULE
Acceptance N.: 20-5600

TEST MANAGEMENT
Coronati Consulting S.r.l 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"

TEST SAMPLE IDENTIFICATION

Name:	**Softmed meditsiiniline kaitsemask**
Sample Typology:	Surgical mask
Composition:	Three layer
Code (REF):	MedmaskSVTAIK
Batch:	MO0006
Manufacturing date:	25.08.2020
Expiry date:	25.08.2022
Sterilization Method:	NOT STERILE
Sterilization Batch:	N/A
Sterilization Date:	N/A
Sterilization Unit:	N/A

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. G. Botti (Consultant)	Verifed and Approved by: Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
28/09/2020	00	First Issue	Giulia Botti	

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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Coronati Consulting srl - Tel. 0535-611533 Fax 0535-410441- E-mail: info@coronaticonsulting.it Web: www.coronaticonsulting.it

RESULTS

TEST	REQUIREMENTS			RESULTS	REPORT	LABORATORY FACILITY
	Type I [(a)]	Type II	Type IIR			
Bacterial filtration efficiency (BFE), (%)	≥95	≥98	≥98	**99,83**	6437-20 By Coronati Consulting lab	Eurofins Biolab Srl – Department Eurofins Cosmetics and Personal Care
Differential pressure (Pa/cm^2)	<40	<40	<60	**34,76**	5900-20 By Coronati Consulting lab	Coronati Consulting Lab
Splash resistance (kPa)	Not required	Not required	≥16	**PASS**	6201-20 By Coronati Consulting lab	Eurolab Srl
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	**PASS**	5991-20 By Coronati Consulting lab	Coronati Consulting Lab
(a) Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by health care professionals in an operating room or in other medical settings with similar requirements.						

CONCLUSIONS

According to the results obtained, the tested sample can be classified as **Type I, Type II and Type IIR medical face mask** following EN 14683 requirements.

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