

Consultancy and Laboratory Services for Biomedical Quality

SUMMARY TEST REPORT according to EN 14683

REPORT N. 8408-20 Rev. 01

(The present document cancels and replaces Report N. 8408-20 Rev.00 already sent)

Customer: Vajda Papír Kft.

51 Nemedi ut - Dunaharaszti, H-2330, Hungary

TIME SCHEDULE

Acceptance N.: 20-8520

TEST MANAGEMENT

Coronati Consulting S.r.I 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: Ooops! Professional Face Mask

Sample Typology: disposable 3 ply face mask Composition: nonwoven, earloop, noseclip

Code (REF): NOT PROVIDED Batch: FM1202009

Manufacturing date: 29 September 2020 Expiry date: 28 September 2025

Sterilization Method: Not sterile
Sterilization Batch: N/A
Sterilization Date: N/A

Sterilization Unit:

The information concerning the test sample were provided by the Customer. All data related to the test sample are under the responsibility of

N/A

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the Customer and have not been verified by the test laboratory.	
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Issue Date	Rev.	Change Description	Dr. Leonardo Crespi (Consultant)	Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
11/12/2020	00	First Issue	Dr. Leonardo Crespi	
11/01/2021	01	Inclusion of splash test results	Leands Cryn	Horonof-

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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RESULTS

TECT	REQUIREMENTS			DECILITE	REPORT	LABORATORY
TEST	Type I (a)	Type II	Type IIR	RESULTS	REPURI	FACILITY
Bacterial filtration efficiency (BFE), (%)	≥95	≥98	≥98	98,67	8132-20 By Coronati Consulting lab	Eurofins Biolab Srl – Department Eurofins Cosmetics and Personal Care
Differential pressure (Pa/cm²)	<40	<40	<60	38	8137-20 By Coronati Consulting lab	Comolab, Qualità e logistica srl
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	PASS	6131-20 By Coronati Consulting lab	Coronati Consulting Lab
Splash resistance (kPa)	Not required	Not required	≥16	PASS	Report dated 2020/01/08	University of Pécs – Department of Biochemistry and Medical Chemistry

⁽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

requirements.

End of Report

According to the results obtained, the tested sample can be classified as Type IIR medical face mask following EN 14683