

**SUMMARY TEST REPORT**  
according to EN 14683 and ISO 10993-1

REPORT N. 6243-20 Rev. 00

Customer: **Balerina-Czech, s.r.o.**  
Prestavicka 1447 - Mnichovo Hradiste 295 01 - Czech Republic

**TIME SCHEDULE**

Acceptance N.: 20-6102

**TEST MANAGEMENT**

Coronati Consulting S.r.l Via L. Gavioli, 3 I-41037 Mirandola (MO) Certified ISO 9001/ ISO 13485

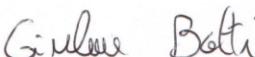

**REFERENCE DOCUMENTS**

- UNI EN 14683:2019 "Medical face masks - Requirements and test methods"
- ISO 10993-1:2018 "Biological evaluation of medical devices Evaluation and testing within a risk management process"

**TEST SAMPLE IDENTIFICATION**

Name: **Disposable Face Mask BFE 99 Balerina**  
 Sample Typology: medical face mask  
 Composition: 3 layers medical face mask  
 Code (REF): DFM3-2020  
 Batch: 2020-29-06-49  
 Manufacturing date: 2020-29-06  
 Expiry date: 2023-29-06  
 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)	Verified and Approved by: Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
18/09/2020	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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## RESULTS

TEST EN 14683	REQUIREMENTS			RESULTS	REPORT by Coronati Consulting lab	LABORATORY FACILITY
	Type I <sup>(a)</sup>	Type II	Type IIR			
Bacterial filtration efficiency (BFE), (%)	≥95	≥98	≥98	<b>99,91</b>	5030-20	Eurofins Biolab Srl – Department Eurofins Cosmetics and Personal Care
Differential pressure (Pa/cm <sup>2</sup> )	<40	<40	<60	<b>56,49</b>	5729-20	Coronati Consulting Lab
Splash resistance (kPa)	Not required	Not required	≥16	<b>PASS</b>	5029-20	Eurolab Srl
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	<b>PASS</b>	5523-20	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.

BIOCOMPATIBILITY TEST ISO 10993-1	STANDARD	RESULTS	REPORT N° by Coronati Consulting lab	LABORATORY FACILITY
Cytotoxicity test	ISO 10993-5 ISO 10993-12	<b>Under the assay conditions the extract of the sample is considered NON-CYTOTOXIC.</b>	4979-20	Coronati Consulting Lab
In vitro analysis of the pro-sensitising potential	OECD 442E	<b>On the basis of the results, the eluted sample "Disposable Face Mask BFE 99 Balerina" does not affect in this in vitro model the expression of the investigated markers in immunocompetent cells, and hence it does not show any stimulating potential on the immune cellular response mediated by monocytes/macrophages.</b>	5379-20	Abich Srl
In Vitro Skin Irritation on Reconstructed Human Epidermis Test Method	OECD 439	<b>On the basis of the results, the sample "Disposable Face Mask BFE 99 Balerina" is NOT A SKIN IRRITANT.</b>	5778-20	Abich Srl

## CONCLUSIONS

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

According to the results obtained, the tested sample can be considered as **biocompatible** following ISO 10993-10 and EN 14683 requirements.

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