Consultancy and Laboratory Services for Biomedical Quality

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

REPORT N. 4756-20 Rev. 01

(The present document cancels and replaces Report N. 4756-20 Rev.00 already sent)

Customer: Granberg AS
Bjoavegen 1442, 5584 Bjoa - Norway

TIME SCHEDULE
Acceptance N.: 20-4214

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:	**Granberg ® Medical Face Mask**
Sample Typology:	Surgical face masks
Composition:	Polypropylene, Polyurethane (earloop), Polypropylene + iron (nose clamp)
Code (REF):	210.0022E and 210.0023
Batch:	N/A
Manufacturing date:	01.06.2020
Expiry date:	01.06.2022
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: (Consultant)	Verified and Approved by: (Managing Director Laboratory)
13/07/2020	00	First Issue	Dr. G. Botti	Dr. Renzo Giovanni Coronati
01/09/2020	01	Revision to include biocompatibility tests results and 210.0023 product code that is identical to 210.0022E code except for packing mode. Update of results table.	Giulia Botti	R Coronati

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.

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RESULTS

TEST EN 14683	REQUIREMENTS			RESULTS	REPORT	LABORATORY FACILITY
	Type I [(a)]	Type II	Type IIR			
Bacterial filtration efficiency (BFE), (%)	≥95	≥98	≥98	**99,8**	4741-20 By Coronati Consulting lab	Eurofins Biolab Srl – Department Eurofins Cosmetics and Personal Care
Differential pressure (Pa/cm^2)	<40	<40	<60	**48,4**	4703-20 By Coronati Consulting lab	Coronati Consulting Srl
Splash resistance (kPa)	Not required	Not required	≥16	**PASS**	4743-20 By Coronati Consulting lab	Eurolab Srl
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	**PASS**	4598-20 By Coronati Consulting lab	Coronati Consulting Srl

(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 and EN 14683	STANDARD	RESULTS	REPORT N°	LABORATORY FACILITY
Cytotoxicity test	ISO 10993-5:2009 Annex A EN 14683 par.5.2.6	**Under the assay conditions the extract of the sample is considered NON-CYTOTOXIC.**	4418-20 By Coronati Consulting lab	Coronati Consulting Srl
Assessment of allergic contact dermatitis potential through the reduced local lymph node assay (rLLNA)	ISO 10993-10 par.7.2 EN 14683 par.5.2.6	**On the basis of the results, the sample "Granberg®" DID NOT SHOW ANY SKIN SENSITIZING POTENTIAL.**	5380-20 By Coronati Consulting lab	Abich Srl
Skin irritation test	ISO 10993-10 sec.6.3 EN 14683 par.5.2.6	**On the basis of the results, interpreted according to ISO 10993-10:2010, the test sample "Granberg ®" must be considered NEGLIGIBLY IRRITANT for the skin.**	5716-20 By Coronati Consulting lab	Eurofins Biolab 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----------

GranberG®
FEARLESS PERFORMANCE®

To whom it might concern,

We hereby conform, that masks art. 210.0022E are identical and produced in the same factory as masks art. 210.0023, the only difference being their packing mode.

Ole Marthon Granberg
Managing director

07.08.2020

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