

RAPPORTO DI PROVA N° 7.183_20
Committente: Bristol Mask Limited

 Unit 2B Barton Hill Trading Estate Herapath Street BS59R
 Bristol - -

Settore:	DISPOSITIVI MEDICI	Temp. all'arrivo:	Ambiente
Categoria merceologica:	Dispositivi medici	Data di prelievo:	01/07/2020
Prodotto dichiarato dal committente:	3Play Face Mask with Ear Loops	Data di ricevimento:	01/07/2020
Punto di campionamento:	Sede aziendale	Data inizio:	01/07/2020
Procedura di campionamento:	*** a cura del Committente	Data fine:	08/07/2020
Tipo imballaggio/contenitore:	Busta in plastica		
Operatore campionamento:	Committente		
Verbale di campionamento:	MD RRO MPAdm 5.183 consegna campioni ore 12.00		
Quantità conferita:	24 pz		
Sugello/Contratto:			

Il presente rapporto di prova riguarda esclusivamente il campione dichiarato e sottoposto ad analisi, ove il campionamento non venga effettuato dal laboratorio i dati di prelievo sono sotto la responsabilità del committente e i risultati si riferiscono al campione così come ricevuto. Il rapporto di prova non può essere riprodotto parzialmente se non previa approvazione scritta del laboratorio che lo emette.

DESCRIZIONE PROVE	VALORI	UNITA' DI MIS.	INCERTEZZA ^{oo}
Bioburden medio totale (TSA e SDA) Metodo: UNI EN ISO 11737-1:2018	18	ufc/g	
* Efficienza di Filtrazione Batterica media Metodo: UNI EN 14683:2019 App.B	99,9	%	
* Pressione Differenziale media Metodo: UNI EN 14683:2019 App.C	13,47	Pa/cm2	

Note:

Vedi allegati

Il Responsabile di Laboratorio
Dr.ssa VALERIA D'OSTUNI

 Data di emissione **08/luglio/2020**

 * **Prova non accreditata da ACCREDIA**
^{oo} Incertezza estesa calcolata applicando un fattore di copertura pari a 2 corrispondente ad un livello di fiducia circa del 95%

^{ooo} Il campionamento è escluso dall'accREDITAMENTO

Fine del rapporto di prova N° 7.183_20

Cap.Soc.I.V.€15.000,00
CF/P.IVA Registro Imprese Lecce 03689990756
REA 238498

Via delle Anime, 87- LECCE
Tel/fax 0832242087
www.microbiostudio.it

Test Report N° 7.183_20

These results relate only to sample tested. The report shall not be reproduced without prior written approval of Studio di Microbiologia ed Ecologia srl.

Customer Name & Address: Bristol Mask Limited
Unit 2B Barton Hill Trading Estate
Herapath Street BS59R
Bristol

SAMPLE PARTICULARS:

SAMPLE DESCRIPTION : 3PLAY FACE MASK WITH EAR LOOPS

SAMPLE RECEIPTED DATE : 2020-07-01

REPORT RECEIPT : 5.183

SAMPLED COLLECTED BY : BRISTOL MASK LIMITED

SAMPLED POINT : BRISTOL MASK LIMITED

TEST STARTED ON :2020-07-01

TEST COMPLETED : 2020-07-08

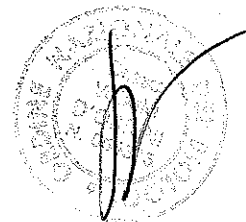
RESULTS OF ANALYSIS

TEST	TEST METHOD	UNIT	RESULT
*MICROBIAL CLEANLINESS TEST (BIOBURDEN)	UNI EN ISO 11737-1:2018	ufc/g	18
*BACTERIAL FILTRATION EFFICIENCY (BFE)	UNI EN 14683:2019 App. B	%	99.9
*BREATHABILITY AS DIFFERENCIAL PRESSURE	UNI EN 14683:2019 App. C	Pa/cm	13.47
End of report			

* see attachments

Laboratory manager

Dr.ssa Valeria D'Ostuni



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Attached to the Test Report N. 7.183.20
Sample: 3Play Face Mask with Ear Loops

TEST: BIOBURDEN (UNI EN ISI 11737-1:2018)

Sample	N°	1	2	3	4	5	Mean
Weight	g	2.80	2.78	2.77	2.79	2.76	2.78
TSA	cfu/item	50	48	49	50	51	50
SDA	cfu/item	0	0	0	0	0	0
Total Bioburden	cfu/item	50	48	49	50	51	50
Total Bioburden	cfu/g	18	17	18	18	18	18

Following the tests performed according to the EN 14683: 2019 standard, it was found that the product tested respects the Bioburden requirements of the standard (paragraph 5.2.2 and appendix B) for type I and II.



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SAMPLE: 3Play Face Mask with Ear Loops

Standard EN 14683:2019 – 5.2.2 Bacterial filtration efficiency (BFE)

The test methods for the in vitro evaluation of the Bacterial Filtration Effectiveness (BFE) are in accordance with the UNI EN 14683: 2019 standard "Facial masks for medical use - requirements and test methods".
The test is conducted on a sample with a diameter of approximately 50 mm.

A bacterial aerosol is generated upstream of the sample (bacteria: Staphylococcus aureus NCTC 6571),
Downstream of the sample, a microbiological sampling is done to collect any bacteria that may be present. After incubation at 37 ° C for 24 - 48 hours, the microorganisms are counted.
2 positive controls are performed to evaluate the number of bacteria collected in the absence of testing sample.

BFE is calculated:

$$BFE (\%) = (C - T)/C \times 100$$

- C = average CFU count value in positive controls (without sample).
- T = average CFU count value in the samples downstream of the sample under examination.

Size of the test area		50.0 cm ²				
Side of the sample exposed to the aerosol		Internal side				
Average value of the total plate count of the two positive controls					2.0 x 10 ⁵	cfu
Average value of the total plate count of the negative control					<1	cfu
Sample	1	2	3	4	5	Mean
BFE (%)	99.9	99.9	99.9	99.9	99.9	99.9

Following the tests carried out according to the EN 14683: 2019 standard, it was found that the product tested respects the bacterial filtration efficiency requirements of the standard (paragraph 5.2.2 and appendix B) for type I and II.



TEST REPORT N. 101_20

DEVICE

Bristol mask limited 3 ply face mask with ear loops

Reference legislation: UNI EN 14683:2019 App.C
Method for determining respirability (Differential pressure)
Measured quantity: Differential pressure ΔP

Calculation of the differential pressure ΔP (App.C.5)

Differential pressure: $\Delta P = (X_{m1} - X_{m2}) / 4,9$ [Pa/cm²]

where:

- X_{m1} Pressure in Pa, measured on the low pressure side of the material;
- X_{m2} Pressure in Pa, measured on the high pressure side of the material;
- 4,9 is the area in cm² of the test material;
- ΔP is the differential pressure per cm² of test material expressed in Pa.

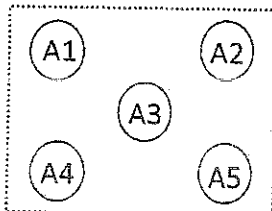
Provini/Test

Type: Complete mask
Number: 5
Number of test areas: 5, circular with a diameter of 25 mm, for each specimen (template)
Flow direction: from inside the mask to the outside of the mask
Conditioning: (21 +/- 5) °C e (85 +/- 5) % of relative humidity for at least 4 hours.

Test area layout

Test areas:

- Area 1 (A1)
- Area 2 (A2)
- Area 3 (A3)
- Area 4 (A4)
- Area 5 (A5)



Number and locations of test areas with a

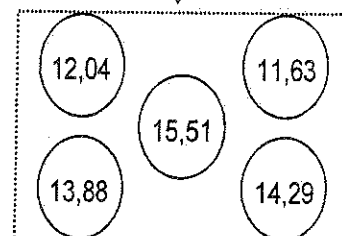
Average values of the differential

Average values by area of ΔP for the 5 specimens examined

Test result

ΔP [Pa/cm²]: differential pressure for each area tested by the specimen

Provino number	Area 1 A1	Area 2 A2	Area 3 A3	Area 4 A4	Area 5 A5	ΔP [Pa/cm ²]
1	12,24	13,27	17,55	12,24	14,29	13,92
2	12,24	10,41	13,88	13,47	13,47	12,69
3	11,63	11,02	14,90	15,71	15,31	13,71
4	12,45	10,82	15,31	15,31	14,29	13,63
5	11,63	12,65	15,92	12,65	14,08	13,39



Air flow rate during the test : 8 [l/min]

Average differential pressur
calculated on 5 specimens:
13,47 [Pa/cm²]

Means: 12,04 11,63 15,51 13,88 14,29 13,47

OPERATOR: MASSIMILIANO VELLICO (+FM) DATE AND SIGNATURE 02/07/2020

THE CUSTOMER FOR ACKNOWLEDGMENT DATE AND SIGNATURE 02/07/2020