



www.eurodisposables.com

Euro Disposables- Import/Export International Business & Market Development e.U.

EU Identification Number: ATU68505129

Doktor.-Theodor- Gugl- Weg 16, 5081 Anif AUSTRIA

info@eurodisposables.com

Tel: +436641644943

3 LAYERS PP FACE MASK MEDICAL WITH EARLOOPS

CE CERTIFICATIONS UNDER DIRECTIVE 93/42/ECC, ISO 9001:2016 BY TÜV SÜD; Sanitation and quality in accordance with CE, FDA, ISO9001standards, EN14683, TYPE IIR, ACCORDING TO EN ISO 11377-1:2018

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;

Fail = Fail customer requirements;

= No comment;

N.D. = Not detected.

TÜV
Photo of Samples



- Soft, lightweight, Comfortable, odourless
- Fiberglass free, Latex free ear loops
- Non-irritating to skin
- Specification: Material: 3Ply 25GSM PP+25 GSM filter +pp 25GSM PP
- Dimension: 17.5x9.5cm (+/-0.5cm, EARLOOP)
- Packing: 20pcs per bag, 2 bags per box= 40 pieces, 50 boxes per carton: Total Units: 2.000. Export Carton size 60 cm*45.5cm*49cm 10 kg/ gross weight

CE



www.eurodisposables.com

Euro Disposables- Import/Export International Business & Market Development e.U.

EU Identification Number: ATU68505129

Doktor.-Theodor- Gugl- Weg 16, 5081 Anif AUSTRIA

info@eurodisposables.com

Tel: +436641644943

Test Report No.: 15099 6088001
Report Date: 13 March 2020



Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	19	3	22	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤ 30 CFU/g tested.	Pass
2#	11	3	14		
3#	8	8	8		
4#	6	2	8		
5#	7	3	10		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D

CE



Test Report No.: 15099 6088001

Report Date: 13 March 2020



Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.9% Specimen 3#: 99.8% Specimen 4#: 99.8% Specimen 5#: 99.7%
2	Differential Pressure Test	25.3 Pa/cm ²
3	Synthetic Blood Penetration Test	Specimen 1#-13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 22 CFU/g Specimen 2#: 14 CFU/g Specimen 3#: 10 CFU/g Specimen 4#: 8 CFU/g Specimen 5#: 10 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Surgical masks
Specification : M
Lot Number : 200229
Sample Receiving Date : 2020-03-10

3. Test Method

EN 14683:2019+AC:2019(E) Annex B