

# EC CERTIFICATE

MDC MEDICAL DEVICE CERTIFICATION GMBH  
Notified Body 0483  
Herewith certifies that

**O+ PLUS FRANCE**  
**RCS STRASBOURG DIREN 815 185 012**  
**11 Route de Brumath**  
**67800 HOENHEIM,**  
**FRANCE**

For the scope  
three-ply surgical face mask  
has introduced and applies a  
**Full Quality Assurance**  
for the desing, manufacture and final inspection.

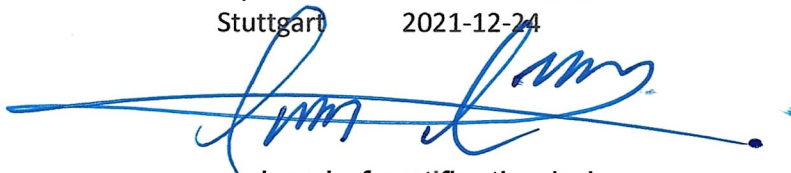
The mdc audit has proven that this full Quality Assurance  
Meets all requirements according to

**Annex I - excluding**  
**Section 4 of the council**  
**Directive 2017/ 745**

Of 14 June 1993 concerning medical devices.

The surveillance will be help as specified in annex I,  
Section 4.

Validfrom	2021-12-24
Validuntil	2023-12-24
Registration no.	D1055302211
Report no.	P15-05050-1017F1
Stuttgart	2021-12-24



head of certification boby



## ANALYSIS REPORT

Report No. : 2024261E- F1                      Report Date : 24/12/2021

Applicant    : O+ Plus France

Address    : RCS STRASBOURG DIREN 815 185 012 11 Route de Brumath 67800 HOENHEIM, FRANCE

Sample    : 3 Ply Surgical Face Mask

Sample Package                                  : Carton box

Sample Amount                                  : 50 Pieces

Sampling Point                                    : -

Sampling Date                                    : -

Sample Lot No.                                    : -

Production Date                                 : 12/2021

Packing Date                                     : -

Expire Date                                        : 12/2023

Producer Company                              : -

Product No                                        : -

Supplier Number                                : -

Sample Receiving Time                        : 22/12/2021 11:35:00

Analysis Beginning Time                      : 22/12/2021 11:45:00

Analysis Completion Time                    : 24/12/2021

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
<b>Bacterial Filtration Efficiency</b>								
BFE - 1	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*) 122, 124, 129
BFE - 2	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*) 122, 124, 129
BFE - 3	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*) 122, 124, 129
BFE - 4	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*) 122, 124, 129
BFE - 5	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*) 122, 124, 129
Mean Positive Control Count	cfu	1963	-	-	-	-	EN 14683 - Annex B	(*)
Negative Control Count	cfu	<1	-	-	-	-	EN 14683 - Annex B	(*)
Mean Particle Size (MPS)	µm	3,1	-	-	-	-	EN 14683 - Annex B	(*)

**Linusa Jonas**  
Microbiology Laboratory Responsible

Approved by  
24/12/2021  
**Emile Lukas**  
Laboratory Manager

## ANALYSIS REPORT

Report No. : 2024261E- F1

Report Date : 24/12/2021

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
<b>Microbial Limit - Bioburden</b>								
Bioburden - 1	cfu/g	15	≤30	≤30	≤30	97	ISO 11737-1	(*) 120, 131
Bioburden - 2	cfu/g	16	≤30	≤30	≤30	97	ISO 11737-1	(*) 120, 131
Bioburden - 3	cfu/g	10	≤30	≤30	≤30	97	ISO 11737-1	(*) 120, 131
Bioburden - 4	cfu/g	8	≤30	≤30	≤30	97	ISO 11737-1	(*) 120, 131
Bioburden - 5	cfu/g	13	≤30	≤30	≤30	97	ISO 11737-1	(*) 120, 131

**Source of Limit Ranges** : 97 Medikal Yüz Maskelerinin Test Metodları ve Performans Gereksinimleri (EN 14683)

**Method** ISO : International Organization for Standardization

**Information**

120 : Bioburden : Aerobic Bacteria and Mold-Yeast  
 Pozitive Controls : Bacillus atrophaeus  
 Extract Fluid : Peptone, Tween with Sodium Chloride  
 Extract Fluid Volume : 300 mL  
 Plating Method : Membrane Filtration  
 Agar Medium : Tryptic Soy Agar for Aerobic Bacteria Count and Sabouraud Dextrose Agar with Chloramphenicol for Mold and Yeast Count  
 Recovery Efficiency : Repetitive Rinse Method  
 Aerobic Bacteria : Plates are incubated 3 days at 30-35°C, then enumerated.  
 Yeast - Mould : Plates are incubated 5-7 days at 20-25°C, then enumerated.

122 : Conditioning Parameters : 85± 5 relative humidity and 21± 5 °C de minimum 4 hours

124 : Flow rate during testing : 28.3 L/dk  
 Test performed with the inside of the medical face mask in contact with the bacterial challenge.

129 : The mask analyzed according to the results of Bacterial Filtration Efficiency (BFE) provides EN 14683 Table 1. Type I, Type II and Type IIR limits.

131 : The mask analyzed according to the results of Microbial Limit - Bioburden provides EN 14683 Table 1. Type I, Type II and Type IIR limits.

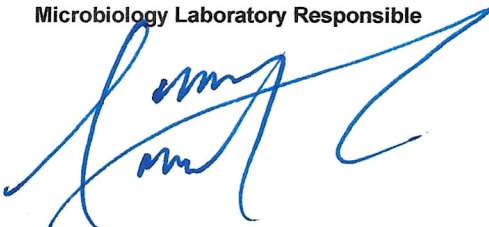
**R1** : This code means correction at this report. 14/09/2021 dated and 2024261E numbered report is invalid. "Sample Type" information has been revised based on customer request. Our report has been rearranged as new report number is 2024261E-R1.

**Note**

- When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
- Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
- Analysis report covers samples/sampling that comes to the laboratory.
- This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
- This report shall not be used official purposes related to Enviromental Regulations.
- The test report without sign is not valid.
- (\*) This parameter is covered by our accreditation scope.

End of Report

**Linusa Jonas**  
 Microbiology Laboratory Responsible



**Approved by**  
 24/12/2021  
**Emile Lukas**  
 Laboratory Manager



## ANALYSIS REPORT

Report No. : **2025147E- F1**                      Report Date : 24/12/2021

Applicant    : O+ Plus France  
 Address    : RCS STRASBOURG DIREN 815 185 012 11 Route de Brumath 67800 HOENHEIM, FRANCE

Sample     : 3 Ply Surgical Face Mask

Sample Package                                    : Carton box  
 Sample Amount                                    : 50 Pieces  
 Sampling Point                                    : -

Sampling Date                                     : -  
 Sample Lot No.                                    : -  
 Production Date                                   : -  
 Packing Date                                      : -  
 Expire Date                                        : -  
 Producer Company                               : -  
 Product No                                        : -  
 Supplier Number                                 : -  
 Sample Receiving Time                         : 22/12/2021 11:35:00

Analysis Beginning Time                        : 22/12/2021 11:45:00  
 Analysis Completion Time                      : 24/12/2021

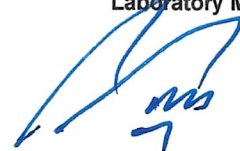
Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
<b>Differential Pressure</b>								
DP - 1	Pa/cm <sup>2</sup>	27	< 40	< 40	< 60	97	EN 14683 - Annex C	(*) 122, 123, 126, 144
DP - 2	Pa/cm <sup>2</sup>	21,93	< 40	< 40	< 60	97	EN 14683 - Annex C	(*) 122, 123, 126, 144
DP - 3	Pa/cm <sup>2</sup>	20	< 40	< 40	< 60	97	EN 14683 - Annex C	(*) 122, 123, 126, 144
DP - 4	Pa/cm <sup>2</sup>	23,13	< 40	< 40	< 60	97	EN 14683 - Annex C	(*) 122, 123, 126, 144
DP - 5	Pa/cm <sup>2</sup>	22,24	< 40	< 40	< 60	97	EN 14683 - Annex C	(*) 122, 123, 126, 144

**Linusa Jonas**  
Laboratory Responsible



Approved by  
24/12/2021

**Emile Lukas**  
Laboratory Manager



## ANALYSIS REPORT

Report No. : 2025147E-F1

Report Date : 24/12/2021

**Source of Limit Ranges** : 97 Medikal Yüz Maskelerinin Test Metodları ve Performans Gereksinimleri (EN 14683)

**Method** EN : European Standard

**Information**

- 122 : Conditioning Parameters :  $85 \pm 5$  relative humidity and  $21 \pm 5$  °C de minimum 4 hours
- 123 : Flow rate during testing : 8 L/dk
- 126 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type I, Type II and Type IIR limits.
- 144 : The test was applied from the inner surface on the mask to the outer surface, as required by the standard.

R1 : This code means correction at this report. 13/09/2021 dated and 2025147E-R1 numbered report is invalid. "Type of Sample" information has been revised based on the customer request. Our report has been rearranged as new report number is 2025147E-R2.

**Note**

1. When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
2. Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
3. Analysis report covers samples/sampling that comes to the laboratory.
4. This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
5. This report shall not be used official purposes related to Enviromental Regulations.
6. The test report without sign is not valid.
7. (\*) This parameter is covered by our accreditation scope.

End of Report

Linusa Jonas  
Laboratory Responsible



Approved by

24/12/2021

Emile Lukas  
Laboratory Manager

