EC CERTİFİCATE

MDC MEDİCAL DEVİCE CERTİFİCATİON GMBH
Notified Boby 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 reguirements 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

medical device certification mdc

Benannt durch/Designated by
ZLG
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone +49-(0)711-253597-0
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Internet http://www.mdc-ce.de

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
Bacterial Filtration Efficiency								
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

MDC MEDİCAL DEVİCE CERTİFICATİON GmbH
D-70191 Stuttgart, Germany

ANALYSIS REPORT

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

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Microbial Limit - Bioburden								
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 incubatede 3 days at 30-35°C, then enumerated.
Yeast - Mould : Plates are incubatede 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

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
Microbiology Laboratory Responsible

Approved by
24/12/2021
Emile Lukas
Laboratory Manager

MDC MEDİCAL DEVİCE CERTİFICATİON GmbH
D-70191 Stuttgart, Germany

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
Differential Pressure									
DP - 1	Pa/cm²	27	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 126, 144
DP - 2	Pa/cm²	21,93	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 126, 144
DP - 3	Pa/cm²	20	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 126, 144
DP - 4	Pa/cm²	23,13	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 126, 144
DP - 5	Pa/cm²	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

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D-70191 Stuttgart, Germany

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± 5 relative humidity and 21± 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 outher 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.
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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

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