PROMASK

Mascarilla quirúrgica

Mascarilla filtrante de 3 capas no reutilizable.
Sin válvula. MEDICA.
Filtración mayor al 98% de las partículas.

Documentación técnica

- Ficha técnica
- Declaración de conformidad
- Test report
- Test report material

Mascarilla quirúrgica

Mascarilla quirúrgica de 3 capas. No reutilizable. MÉDICA. Filtración mayor al 98% de las partículas.

ESPECIFICACIONES:

- Eficiencia de filtrado: BFE > 98%.
- Mascarilla Tipo II.
- No estéril. Filtrado microbiológico.
- No reutilizable.
- Vida útil: 5 años.
- Talla: adultos.
- Dimensiones: 176 x 95 mm.
- Gomas suaves y elásticas para un ajuste confortable en ambos pabellones auditivos.
- No irrita la piel y no causa alergias.

3 capas de protección

Transpirable

COLORES:

- Blanco
- Azul
- Rosa
- Naranja

COMPOSICIÓN:

Mascarilla de 3 capas compuestas de tejido no tejido "Melt Blown" (Polipropileno).
Gomas elásticas de poliéster.

PACKAGING:

- Cajas pequeñas: 50 unidades.
- Cajas distribución: 20 cajas pequeñas, 1000 unidades de mascarillas.
  Dimensiones caja distribución: 52x38x40 cm
  Peso bruto caja distribución: 7,6 kg.

NORMAS Y CERTIFICACIONES:

Este dispositivo es un producto sanitario según la Directiva 93/42 o del Reglamento UE / 2017/745.

Certificado Europeo CE
Nº de informe: 555-15-20-1
UNE EN-14683

Mascarilla certificada en LOTRIC, centro autorizado localizado en Eslovenia.
Número de organismo notificado: 1304.

LOTRIC Metrology Ltd.
Dirección: Selca, 163 - 4227 Selca - Eslovenia
Teléfono: +386 4 51 70 700
E-mail: info@lotric.si
Página web: www.lotric.si

FOTOGRAFÍAS DEL PRODUCTO:

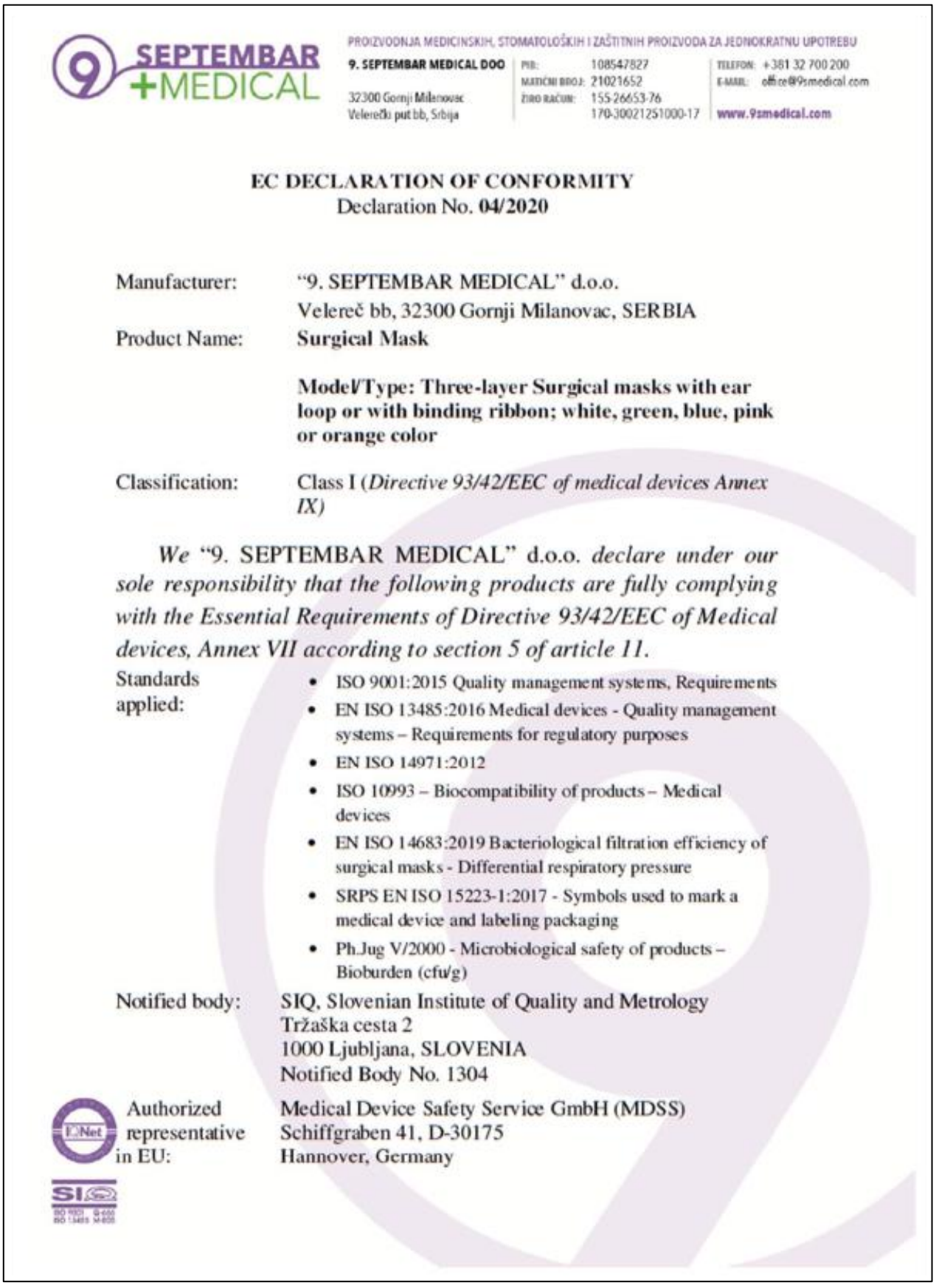
Caja de 50 unidades

INSTRUCCIONES DE USO:

1. Lavarse las manos durante 40-60 segundos antes de manipularla.
2. Tocar solo las gomas de la mascarilla.
3. Colocar la mascarilla sobre la nariz y boca.
4. Pasar las gomas elásticas por detrás de las orejas.
5. Pellizcar la banda metálica para ajustarla a la nariz.
6. Evitar tocar la parte exterior de la mascarilla. Si ocurre, lavar las manos antes y después.
7. Lavar las manos antes de retirarse la mascarilla.
8. Retirarla tocando solo las gomas elásticas.
9. Para desecharla, introducirla en una bolsa de plástico. Depositarla cerrada en la basura y lavar las manos.

Condiciones de almacenaje: Almacenar en un ambiente seco y fresco, alejado de la luz directa del sol y fuentes de calor.

Mascarilla quirúrgica



9 SEPTEMBAR +MEDICAL

PROIZVODNJA MEDICINSKIH, STOMATOLOŠKIH I ZAŠTITNIH PROIZVODA ZA JEDNOKRATNU UPOTREBU

9. SEPTEMBAR MEDICAL DOO
32300 Gornji Milanovac
Velereču put bb, Srbija

PIB: 108547827
MATIČNI BROJ: 21021652
ŽIRO RAČUN: 155-26653-76
170-30021251000-17

TELEFON: +381 32 700 200
E-MAIL: office@9smedical.com
www.9smedical.com

EC DECLARATION OF CONFORMITY
Declaration No. **04/2020**

Manufacturer: "9. SEPTEMBAR MEDICAL" d.o.o.
Velereč bb, 32300 Gornji Milanovac, SERBIA

Product Name: **Surgical Mask**

Model/Type: Three-layer Surgical masks with ear loop or with binding ribbon; white, green, blue, pink or orange color

Classification: Class I (*Directive 93/42/EEC of medical devices Annex IX)*

We "9. SEPTEMBAR MEDICAL" d.o.o. *declare under our sole responsibility that the following products are fully complying with the Essential Requirements of Directive 93/42/EEC of Medical devices, Annex VII according to section 5 of article 11.*

Standards applied:
- ISO 9001:2015 Quality management systems, Requirements
- EN ISO 13485:2016 Medical devices - Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2012
- ISO 10993 – Biocompatibility of products – Medical devices
- EN ISO 14683:2019 Bacteriological filtration efficiency of surgical masks - Differential respiratory pressure
- SRPS EN ISO 15223-1:2017 - Symbols used to mark a medical device and labeling packaging
- Ph.Jug V/2000 - Microbiological safety of products – Bioburden (cfu/g)

Notified body: SIQ, Slovenian Institute of Quality and Metrology
Tržaška cesta 2
1000 Ljubljana, SLOVENIA
Notified Body No. 1304

Authorized representative in EU: Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41, D-30175
Hannover, Germany

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170-3002125100-17

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E-MAIL: office@9smedical.com
www.9smedical.com

G. Milanovac, April 23 th 2020.

Responsible person:
Zoran Jokanović ,director

Zoran Jokanović 364038-0910962 710200
0962710200

Digitally signed by Zoran Jokanović
Date: 2020.08.17 14:59:40 +02'00'

Mascarilla quirúrjica

LOTRIČ METROLOGY

številka certifikata
certificate number
555-15-20-1

CERTIFIKAT O PRESKUSU
TEST CERTIFICATE

naročnik applicant	"9. SEPTEMBAR MEDICAL" d.o.o. Velereč bb, 32300 Gornji Milanovac
lastnik owner	"9. SEPTEMBAR MEDICAL" d.o.o. Velereč bb, 32300 Gornji Milanovac
vzorec sample	Osebna polobrazna maska *Personal face half mask*
proizvajalec manufacturer	9. SEPTEMBAR MEDICAL

identifikacijska številka identification number	**LOT številka** LOT number	**tip maske** mask type
1-5 (SAMPLE 1)	374/20	II

vzorčenje sampling	izvedel naročnik *done by applicant*	**rezultat** result	ustreza *meets*

Podrobnosti so podane v poglavju vzorčenje.
Details are given in chapter sampling.

Podrobnosti so podane v poglavju merilni rezultati.
Details are given in chapter measurement results.

datum preskusa date of test 15. 06. 2020	**datum odobritve** date of approval 19.06.2020
izvedel performed by Žan Kavčič Internally digitally signed	**odobril** approved by Primož Hafner odgovorna oseba *responsible person* digitally signed date: 19.06.2020

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vzorčenje sampling
Vzorčenje je opravil naročnik, ki je poslal označene vzorce v laboratorij.
Sampling was performed by the applicant who sent the samples to the laboratory.

mesto vzorčenja
place of sampling
"9. SEPTEMBAR MEDICAL" d.o.o.
Velereč bb, 32300 Gornji Milanovac

preskusni postopek
test procedure
Preskus je bil izveden po navodilu ML10N211 - z merjenjem padca tlaka pri stalnem pretoku 8 l/min na aparatu za določanje prepustnosti zraka, s predhodno pripravljenimi vzorci v skladu z evropskim standardom EN 14683:2019+AC:2019 (točka 5.2.3 in aneks C). Preskus se je opravil na sredini vzorcu s presekom 20 cm², s tem da se pri nastavitvah aparata upoštevana zahteva standarda za preskus na preseku 4,9 cm².
The test was carried out following the instruction ML10N211 - by measuring the differential pressure at constant flow rate of 8 l/min on an air permeability tester, with conditioned samples in accordance with European standard EN 14683:2019+AC:2019 (section 5.2.3 and annex C). The test was carried out in the center of the sample total area of 20 cm², considering the requirement of the standard for a 4,9 cm² total area when adjusting the tester.

mesto preskusa
place of test
FILC d.o.o.
Laboratorij – mehanski del, Trata 48, 4220 Škofja Loka

pogoji okolja
environmental conditions

		od *from*	do *to*	dovoljeno odstopanje v času meritev *tolerance during measurements*
temperatura zraka *air temperature*	(°C)	23,4	23,4	± 1
relativna vlaga *relative humidity*	(%)	52,2	52,2	± 5

št. certifikata uporabljenih referenčnih etalonov
certificate no. of reference standards used
251-250-19-1, KB21403-18-406.02.15

sledljivost traceability
Pri izvajanju meritev so bili uporabljeni etaloni, ki so sledljivi do nacionalnih etalonov in s tem do mednarodno podprtih realizacij SI-enot. Sledljivost je zagotovljena s kalibracijo v ustreznem kalibracijskem laboratoriju.
The reported measurement values are traceable to the national measurement standards and thus to internationally supported realizations of the SI-units. Traceability is ensured by calibration in the relevant calibration laboratory.

stanje vzorca pri prevzemu (prejeto stanje)
state of sample at acceptance (as found)
Vzorci so bili shranjeni v izvirni embalaži in brez vidnih poškodb.
The samples were stored in original packaging and without visible damage.

Velikost vzorca je / *Sample size is:* 175-180 mm x 90-95 mm (podatek proizvajalca / *manufacturer's information*)

slike vzorca
sample pictures

vzorci pred preskusom (prejeto stanje)
samples prior to the test (as found)

vzorci po preskusu (končno stanje)
samples after the test (as left)

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postopek predpriprave
conditioning procedure

Predpriprava je bila izvedena po navodilu ML10N211 – v klimatski komori v trajanju najmanj 4 ure pri temperaturi 21 °C ± 1 °C in relativno vlago 85 % ± 2,5 % v skladu z evropskim standardom EN 14683:2019 (aneks C).
The conditioning was carried out following the instruction ML10N211 – in the climatic chamber for at least 4 hours at temperature 21 °C ± 1 °C and relative humidity 85 % ± 2,5 % in accordance with European standard EN 14683:2019 (annex C).

merilni rezultati
measurement results

številka vzorca *sample number*	izmerjeni padec tlaka *measured differential pressure* (Pa/cm²)	merilna negotovost *uncertainty* (Pa/cm²)	zahteva *requirement* (Pa/cm²)	
1	13,2	0,5	< 40	✓
2	18,1	0,7	< 40	✓
3	16,2	0,6	< 40	✓
4	13,3	0,5	< 40	✓
5	13,9	0,5	< 40	✓
povprečje *average*	14,9	AQL 4%	< 40	✓

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izjava o skladnosti
statement of compliance

Zahteva je določena glede na evropski standard EN 14683:2019, za padec tlaka (točka 5.2.7).
Requirement is determinate according to European standard EN 14683:2019 for pressure drop (section 5.2.7).

✓ Merilni rezultati so ZNOTRAJ zahtev.
The measurement results are WITHIN the requirements.
✖ Merilni rezultati so ZUNAJ zahtev.
The measurement results are OUTSIDE the requirements.

Izjava o skladnosti je podana brez upoštevanja razširjene merilne negotovosti.
Statement of compliance is based without considering expanded uncertainty.

izjava statement

Podani merilni rezultati se nanašajo izključno na preskušane vzorce in izmerjene vrednosti v času meritev, ki ne zagotavljajo dolgotrajne stabilnosti ali razširjanje rezultatov na ostale vzorce ali serije vzorcev.
The measurement results refer only to the tested item and to the measured values at the time of measurement, which carry no implication regarding the long term stability or disseminating results to other samples or series of samples.

n/a – se ne uporablja
n/a - not applicable

merilna negotovost
uncertainty

Podana razširjena merilna negotovost je podana kot standardna negotovost pomnožena s faktorjem pokritja k = 2, kar za normalno porazdelitev ustreza intervalu verjetnosti približno 95 %. Standardno negotovost smo določili v skladu z EA vodilom EA-4/02 M: 2013.
The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by coverage factor k = 2. which for a normal distribution corresponds to a coverage probability of approximately 95 %. The standard uncertainty of measurement has been determined in accordance with EA Publication EA-4/02 M: 2013.

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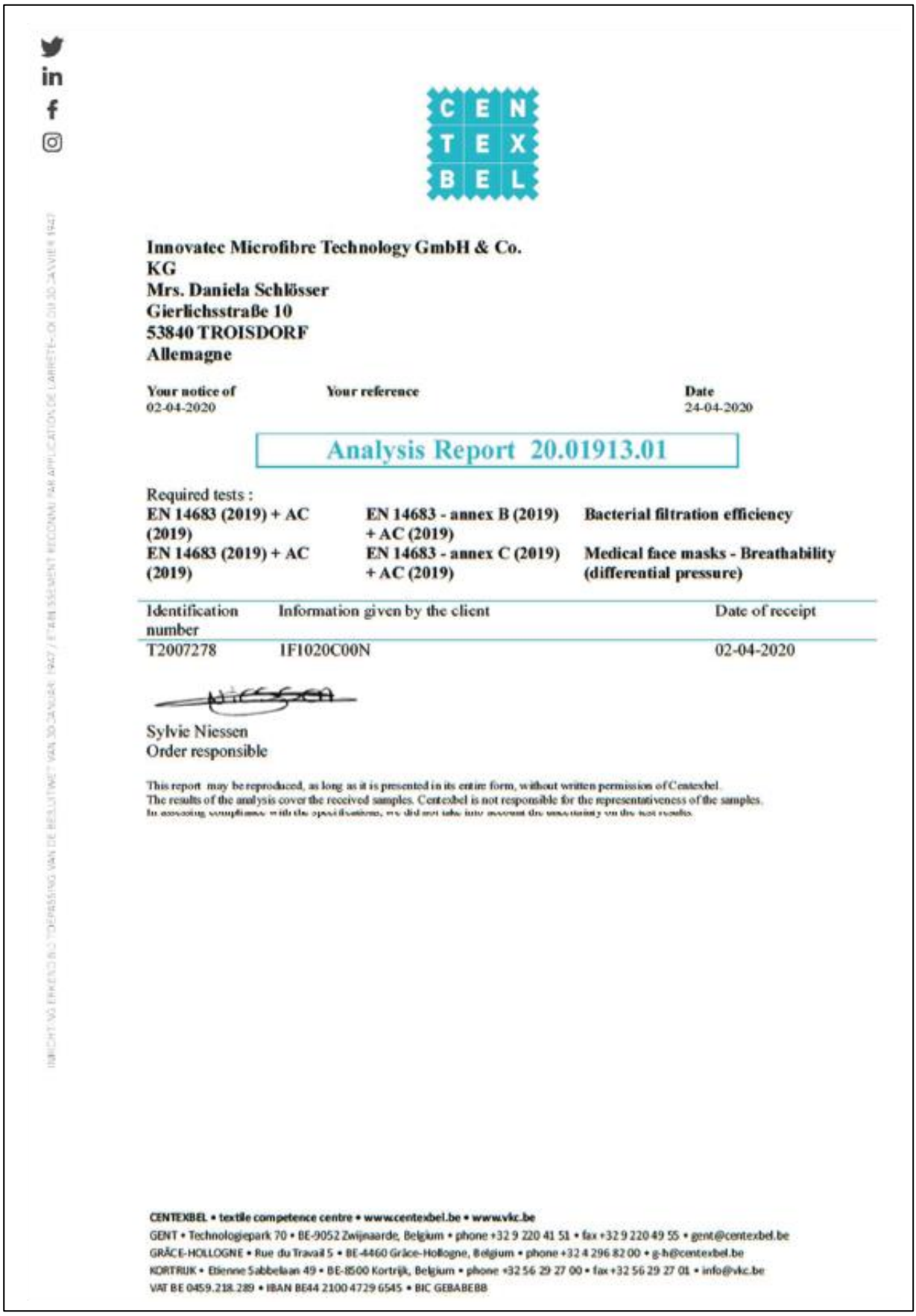

Innovatec Microfibre Technology GmbH & Co.
KG
Mrs. Daniela Schlösser
Gierlichsstraße 10
53840 TROISDORF
Allemagne

Your notice of	Your reference	Date
02-04-2020		24-04-2020

Analysis Report 20.01913.01

Required tests :

EN 14683 (2019) + AC (2019)	EN 14683 - annex B (2019) + AC (2019)	Bacterial filtration efficiency
EN 14683 (2019) + AC (2019)	EN 14683 - annex C (2019) + AC (2019)	Medical face masks - Breathability (differential pressure)

Identification number	Information given by the client	Date of receipt
T2007278	1F1020C00N	02-04-2020

Sylvie Niessen
Order responsible

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The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

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VAT BE 0459.218.289 • IBAN BE44 2100 4729 6545 • BIC GEBABEBB

PROMASK

Reference: **T2007278 - 1F1020C00N**

Bacterial filtration efficiency

Date of ending the test	14-04-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Sample description :	Meltblown filter layer for medical face masks - One layer - White - 20g/m2
Number of tested specimens :	3
BFE Area tested :	± 49 cm²
Test specimen conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the specimen in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	1700 - 3000 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge
Deviation from the standard	The test has not been performed on a mask but only on one layer of the tested material Test result based on 3 instead of 5 samples

Performed in the microbiological lab under the responsibility of Yvette Rogister

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Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} X\ 100$$

With C = mean of the total plate counts for the positive control runs
T = total count for the tested specimen

# test specimen	B (%)
1	99.0
2	98.4
3	97.9

Mean particle size of the bacterial challenge aerosol : 2.8 µm

Controls

Mean positive controls 2290 CFU
Negative control < 1 CFU

This test report is valid for products used in relation to the current Covid-19 health crisis and for products which are not entering the regular distribution channels. Cfr Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat"

Performed in the microbiological lab under the responsibility of Yvette Register

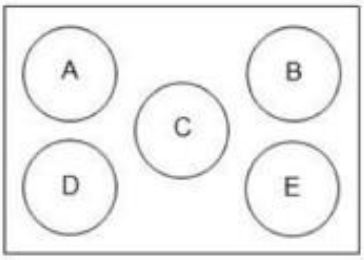
PROMASK

Reference: **T2007278 - 1F1020C00N**

Medical face masks - Breathability (differential pressure)

Date of ending the test	05-04-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Sample description :	Meltblown filter layer for medical face masks - One layer - White - 20g/m2
Number of tested specimens :	5
Number of areas per specimen	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm²
Flow rate :	8 l/min.
Direction of the air flow :	From the inside of the mask to the outside
Test specimen conditioning :	21 ± 5°C and 85 ± 5% RH
Deviation from the standard	The test has not been performed on a mask but on one layer of the tested material

Figure : Distribution of the areas in the test specimen



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Results Δ P

	Test specimen 1	Test specimen 2	Test specimen 3	Test specimen 4	Test specimen 5
Area A	15.7	18.1	18.1	13.6	14.7
Area B	17.9	18.3	15.1	16.1	14.9
Area C	17.5	19.1	14.5	19.4	16.1
Area D	17.9	16.9	16.1	16.1	14.7
Area E	17.5	17.7	18.7	16.9	16.1
Average ΔP (Pa/cm²)	**17.3**	**18.0**	**16.5**	**16.4**	**15.3**

Performed in the microbiological lab under the responsibility of Yvette Register

Mascarilla quirúrgica

Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

9. Septembar Medical d.o.o.
Veloreč bb
32300 GORNJI MILANOVAC
REPUBLIC OF SERBIA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated March 06, 2015

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2015-03-06

Dr. Huan Sun
Senior Manager Registration
MDSS GmbH

MDSS · Medical Device Safety Service · Schiffgraben 41 · 30175 Hannover, Germany