

Mascarilla quirúrgica

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 halfmask

proizvajalec manufacturer 9. SEPTEMBAR MEDICAL

Identifikacijska številka
identification number
1-5 (SAMPLE 1)

LOT številka
LOT number
374/20

tip maske
mask type
II

vzorčenje sampling izvedel naročnik
done by applicant
Podrobnosti so podane v poglavju vzorčenje.
Details are given in chapter sampling.

rezultat result ustreza
meets
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 vzorca 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 izvorni 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)



postopek predpriprave
 conditioning procedure

Predpriprava je bila izvedena po navodilu ML10N211 – v klimatski komori v trajanju najmanj 4 ure pri temperaturi $21 \text{ }^{\circ}\text{C} \pm 1 \text{ }^{\circ}\text{C}$ in relativno vlago $85 \% \pm 2,5 \%$ 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 $21 \text{ }^{\circ}\text{C} \pm 1 \text{ }^{\circ}\text{C}$ and relative humidity $85 \% \pm 2,5 \%$ 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/cm ²)	merilna negotovost uncertainty (Pa/cm ²)	zahteva requirement (Pa/cm ²)	
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.