

GÉPTESZT Kft.
Notified Body No. 2233
registered in the European Union

Address: Jablonka St. 79., Budapest, 1037, HUNGARY
e-mail: nb2233@gepteszt.hu
web: www.gepteszt.hu
Phone: +3612503531



PERSONAL PROTECTIVE EQUIPMENT EU TYPE-EXAMINATION TEST REPORT

EN 149:2001+A1:2009
Particle filtering half mask

The examination and testing of Personal Protective Equipment were carried out in accordance with
MSZ EN ISO/IEC 17025:2005 standard
by GÉPTESZT Kft. Notified Body, identified under number 2233 in the EU

Customer: Nano Medical s.r.o.
Address: 5. kvetna 1640/65, Praha 4, 140 00, CZECH REPUBLIC

Model: NANO MED.CLEAN NM01,
NANO M.ON NM01,
NANO REHABIQ NM01 (same construction, only the model
names are different)

Classification: FFP2 NR

Exhalation valve: NO

Inhalation valve: NO

Uses: non reusable

Project number: GT283

Test report number: VD35/283/2103/E/2233

Project worksheet number: VD-34-2021-283

Date of the test: 2021.03.10 - 03.21.

Samples received date: 2021.03.05.

Sample numbers: 283-1 - 283-46

Attachment: no

Issued: Budapest, 2021.03.25.

GÉPTESZT KFT.
EVE Vizsgáló Laboratórium
NB 2233
1037 Budapest, Jablonka u. 79.
Labor: 1032 Budapest, Gyenes u.12.

Budai Dániel
Director of Laboratory



Relevant standards, directives and requirements:

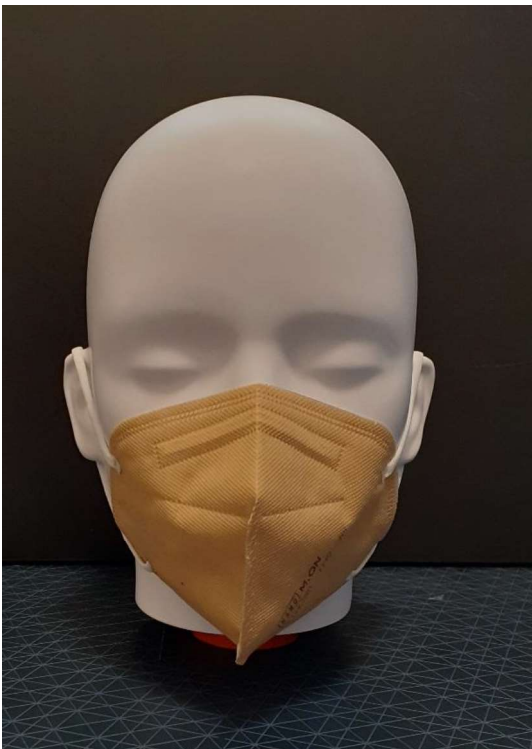
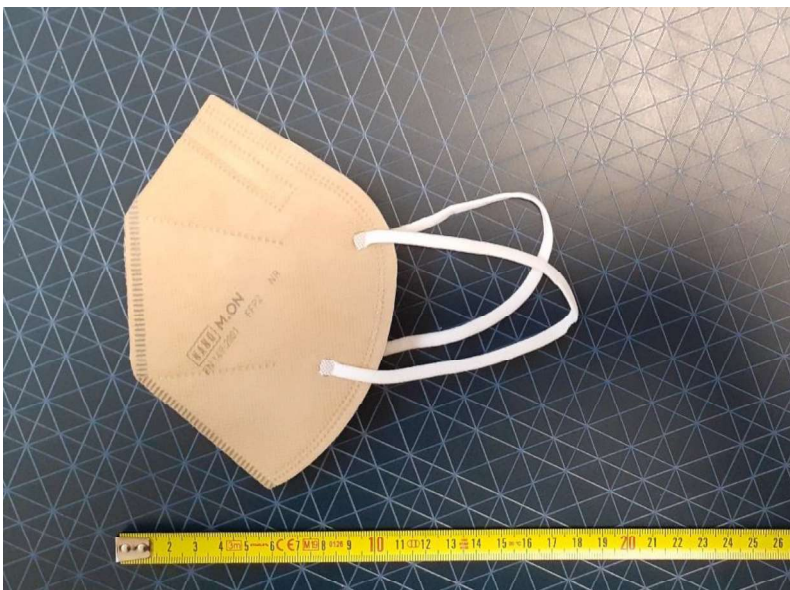
EN 149:2001+A1:2009 Filtering half masks to protect against particles

Description of the sample

The foldable mask is sold in light brown colour and consists of 4 layers:

1. layer: PP spunbond 20 g/m²
2. layer: PP SB /MB 17/20 g/m² + nanolayer PVDF
3. layer: PP spunbond 40 g/m²
4. layer: PP spunbond 40 g/m²

The nose clip is made of 2/6 mini polypropylene, 2 low carbon steel wires; 0,58 mm (± 0.03 mm). The ear loop is made of elastane (polyurethane / polyester) support core, braided with polyamide fibers.





Short description of EU-type tests:

| Requirement | Test method | Description | Result |
|-------------|-----------------|--|--------|
| 7.4 | 8.2 | Packaging | Passed |
| 7.5 | 8.2 | Material | Passed |
| 7.6 | 8.11 | Cleaning and disinfecting | NA |
| 7.7 | 8.4 | Practical performance | Passed |
| 7.8 | 8.2 | Finish of parts | Passed |
| 7.9.1 | 8.5 | Total inward leakage | Passed |
| 7.9.2 | 8.11 | Penetration of filter material: NaCl | Passed |
| 7.9.2 | 8.11 | Penetration of filter material: paraffin oil | Passed |
| 7.10 | 8.4 and 8.5 | Compatibility with skin | Passed |
| 7.11 | 8.6 | Flammability | Passed |
| 7.12 | 8.7 | Carbon dioxide content of the inhalation air | Passed |
| 7.13 | 8.4 and 8.5 | Head harness | Passed |
| 7.14 | 8.4 | Field of vision | Passed |
| 7.15 | 8.2, 8.3.4, 8.8 | Exhalation valve(s) | NA |
| 7.16 | 8.9 | Breathing resistance | Passed |
| 7.17 | 8.10 | Clogging | NA |
| 7.18 | 8.2 | Demountable parts | NA |
| 9 | - | Marking | Passed |
| 10 | - | Information to be supplied by the manufacturer | Passed |

Analysis and details of EU-type test results:

7.4 Packaging

List of all commercial available package:

- NANO M.ON - NM01, 1 pc
- NANO M.ON - NM01, 5 pc
- NANO M.ON - NM01, 10 pc
- NANO M.ON - NM01, 25 pc
- NANO MED.CLEAN - NM01, 5 pc
- NANO MED.CLEAN - NM01, 10 pc
- NANO MED.CLEAN - NM01, 25 pc
- Nano respiratory Rehabiq FFP2 - NM01, 5 pc
- Nano respiratory Rehabiq FFP2 - NM01, 25 p

The material of the packaging: paper 280 g/m²

The packaging gives enough protection against mechanical damage or contamination.

PASSED

7.5 Material

- conditioning S.W.: Sample nr: 283-16 to 283-18
None of the particle filtering half masks have suffered mechanical failure of the facepiece or straps.
- conditioning T.C.: Sample nr.: 283-41 to 283-43
Particle filtering half masks did not collapse.

PASSED

7.6 Cleaning and disinfecting (only for reusable masks)

Because the mask is non-reusable, this test was not carried out.

NA



7.7 Practical performance

The particle filtering half masks are tested by practical performance tests under realistic conditions.

1. Walking test for 10 min
2. Work simulation tests:
 - walking on the level with headroom of (1,3 ± 0,2) m for 5 min;
 - crawling on the level with headroom of (0,70 ± 0,05) m for 5 min;
 - filling a small basket 20x in 10 min;

| Subjects | Samples | Conditioning | Result |
|----------|---------|--------------|--------|
| NT | 283-1 | A.R. | PASSED |
| GL | 283-2 | A.R. | PASSED |

There were not any imperfections related to the wearer's acceptance.

PASSED

7.8 Finish of parts

Parts of the device are likely to come into contact with the wearer have no sharp edges or burrs.

PASSED

7.9.1 Total inward leakage

With sodium chloride aerosol. The masks were in good condition.

Number of subjects were replaced, because of not fitting/facial dimensions:0.....

| Subjects facial dimensions | | | | |
|----------------------------|-----------------|----------------|----------------|-----------------|
| Subject | Face length, mm | Face width, mm | Face depth, mm | Mouth width, mm |
| SA | 110 | 120 | 120 | 50 |
| NT | 122 | 134 | 142 | 57 |
| RE | 115 | 138 | 112 | 48 |
| PA | 120 | 165 | 120 | 70 |
| LA | 123 | 140 | 105 | 60 |
| BF | 110 | 125 | 115 | 50 |
| GL | 90 | 85 | 80 | 50 |
| NA | 130 | 120 | 130 | 50 |
| MD | 117 | 120 | 108 | 60 |
| BP | 120 | 125 | 116 | 57 |

| Subject | Sample | Cond. | Total inward leakage, % | | | | | Mean, % |
|---------|--------|-------|-------------------------|-----------------|--------------|------|------|---------|
| | | | Walk | Head left/right | Head up/down | Talk | Walk | |
| SA | 283-3 | A.R. | 3,93 | 2,88 | 3,12 | 6,91 | 3,69 | 4,11 |
| NT | 283-4 | A.R. | 3,07 | 3,68 | 2,93 | 4,36 | 2,85 | 3,38 |
| RE | 283-5 | A.R. | 3,45 | 3,20 | 3,56 | 5,91 | 3,35 | 3,89 |
| PA | 283-6 | A.R. | 2,90 | 2,99 | 3,08 | 3,84 | 2,73 | 3,11 |
| LA | 283-7 | A.R. | 1,95 | 2,07 | 2,01 | 3,16 | 1,67 | 2,17 |
| BF | 283-8 | T.C. | 1,81 | 1,73 | 1,86 | 6,32 | 1,53 | 2,65 |
| GL | 283-9 | T.C. | 3,77 | 4,24 | 3,84 | 3,37 | 3,81 | 3,81 |
| NA | 283-10 | T.C. | 4,26 | 3,90 | 3,14 | 7,88 | 4,41 | 4,72 |
| MD | 283-11 | T.C. | 3,04 | 3,55 | 3,94 | 4,83 | 3,48 | 3,77 |
| BP | 283-12 | T.C. | 3,51 | 3,62 | 3,11 | 5,74 | 3,28 | 3,85 |

50 out of the 50 individual exercise results for total inward leakage were not greater than 11 % and 10 out of the 10 individual wearer arithmetic means for the total inward leakage were not greater than 8%.

PASSED



7.9.2 Penetration of filter material: NaCl

NaCl aerosol: concentration: 4-12 mg/m³, flow: 95 l/min

| Sample | Conditioning | Penetration, % | Exposure, % |
|---------------------------|--------------|----------------|-------------|
| 283-13 | A.R. | 1,60 | NA |
| 283-14 | A.R. | 1,84 | NA |
| 283-15 | A.R. | 1,00 | NA |
| 283-16 | S.W. | 1,88 | NA |
| 283-17 | S.W. | 1,99 | NA |
| 283-18 | S.W. | 1,76 | NA |
| 283-19 | M.S→T.C. | NA | 2,98 |
| 283-20 | M.S→T.C. | NA | 1,96 |
| 283-21 | M.S→T.C. | NA | 2,56 |
| Maximum permitted: | | 6 % | |

The penetration of the filter material did not exceed the maximum permitted 6 % in case of any masks.

PASSED

7.9.2 Penetration of filter material: paraffin oil

Paraffin aerosol: concentration: 15-25 mg/m³, flow: 95 l/min

| Sample | Conditioning | Penetration, % | Exposure, % |
|---------------------------|--------------|----------------|-------------|
| 283-22 | A.R. | 1,04 | NA |
| 283-23 | A.R. | 0,31 | NA |
| 283-24 | A.R. | 1,36 | NA |
| 283-25 | S.W. | 2,61 | NA |
| 283-26 | S.W. | 3,12 | NA |
| 283-27 | S.W. | 3,05 | NA |
| 283-28 | M.S→T.C. | NA | 1,77 |
| 283-29 | M.S→T.C. | NA | 2,11 |
| 283-30 | M.S→T.C. | NA | 1,94 |
| Maximum permitted: | | 6 % | |

The penetration of the filter material did not exceed the maximum permitted 6 % in case of any masks.

PASSED

7.10 Compatibility with skin

Materials that may come into contact with the wearer's skin are not known to be likely to cause irritation or any other adverse effect to health.

During the Practical performance test there were no problems.

During the Total inward leakage test there were no problems.

PASSED

7.11 Flammability

| Sample | Conditioning |
|--------|--------------|
| 283-33 | T.C. |
| 283-34 | T.C. |
| 283-31 | A.R. |
| 283-32 | A.R. |

The materials used do not present a danger for the wearer and are not of highly flammable nature. The samples did not burn.

PASSED



7.12 Carbon dioxide content of the inhalation air

Air supplied from breathing machine: 25 cycles/min and 2,0 l/stroke, carbon dioxide content of exhaled air 5 V/V%, air flow 0,5 m/s.

Ambient carbon dioxide level: 0,08 % (less than 0,1 %.)

| Sample | CO ₂ V/V% |
|----------------|----------------------|
| 283-35 | 0,48 |
| 283-36 | 0,54 |
| 283-37 | 0,53 |
| Average | 0,52 |

The carbon dioxide content of the inhalation air (dead space) did not exceed an average of 1,0 V/V %.

PASSED

7.13 Head harness

There were no adverse comments regarding security following limited practical performance and total inward leakage testing.

The product satisfied the total inward leakage requirements. See part 7.9.1. for results.

PASSED

7.14 Field of vision

| Sample |
|--------|
| 283-1 |
| 283-2 |

During the practical performance test the field of vision was not affected adversely by wearing mask.

PASSED

7.15 Exhalation valve(s)

NA

7.16 Breathing resistance

| Sample | Conditioning | Inhalation resistance | | Exhalation resistance 160 l/min | | | | |
|--------------------------|--------------|-----------------------|------------|---------------------------------|--------------|----------------|------|-------|
| | | 30 l/min | 95 l/min | ahead | vert.upwards | vert downwards | left | right |
| 283-38 | A.R. | 0,51 | 1,69 | 2,83 | 2,84 | 2,83 | 2,83 | 2,82 |
| 283-39 | A.R. | 0,50 | 1,64 | 2,81 | 2,82 | 2,82 | 2,81 | 2,80 |
| 283-40 | A.R. | 0,54 | 1,67 | 2,85 | 2,85 | 2,84 | 2,85 | 2,84 |
| 283-41 | T.C. | 0,48 | 1,68 | 2,88 | 2,89 | 2,89 | 2,88 | 2,88 |
| 283-42 | T.C. | 0,50 | 1,70 | 2,86 | 2,87 | 2,86 | 2,85 | 2,86 |
| 283-43 | T.C. | 0,51 | 1,71 | 2,87 | 2,88 | 2,87 | 2,87 | 2,86 |
| 283-44 | S.W. | 0,53 | 1,74 | 2,94 | 2,95 | 2,94 | 2,94 | 2,93 |
| 283-45 | S.W. | 0,55 | 1,78 | 2,97 | 2,97 | 2,97 | 2,96 | 2,97 |
| 283-46 | S.W. | 0,56 | 1,79 | 2,96 | 2,97 | 2,95 | 2,96 | 2,96 |
| Maximum permitted | | 0,7 | 2,4 | 3,0 | | | | |

None of the measured values exceeded the maximum values.

PASSED

7.17 Clogging

The optional dolomit clogging test was not required by manufacturer.

NA



7.18 Demountable parts

The device does not contain demountable parts.

NA

9. Marking

The marking information is complete and clearly and durably marked on the packaging.

The marking information is complete and clearly and durably marked on the particle filtering half mask.

PASSED

10. Information to be supplied by the manufacturer

Information to be supplied by the manufacturer accompany every smallest commercial available package and contain all information necessary for trained and qualified persons.

PASSED

Result of EU-type test:

The above described **NANO MED.CLEAN NM01, NANO M.ON NM01, NANO REHABIQ NM01 particle filtering half mask** at the time of the test **conformed** to the test requirements of EN 149:2001+A1:2009 class FFP2 NR at the close date of test report.

E N D O F T H E T E S T R E P O R T