

Our **CE certified** mark guarantees our conformity with health, safety, and environmental protection standards for FP mask products sold within the European Economic Area (EEA), as described in:

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Our CE conformity is recognized worldwide the manufacturer declaration that the product meets EU standards for health, safety, and environmental protection.

Our four digit identification number of the Notified Body can be found (within the coming period) on our website as the number was pending during the production of this product.

Our CE mark indicates that we declare our product is produced in compliance with set regulations and may be sold freely in any part the European Economic Area, irrespective of its country of origin.

At this moment, our internal production control is module A self-certificated assessment to ensure safe use of our products.

Our CE number is mandatory on our product packaging within the European Union, but during production this number was still pending. FP mask guarantees the number is available but production time limitation during this covid19 crisis forced us to publish the pending number on our website.

Responsibility for our CE marking lies with FP mask for any of our products put on the market in the EU. A technical file with our conformity assessment is available on request by any official body to confirm our compliance with regulated standards.

Our CE marking constitutes we acted with due care and affirmation to regulations as manufacturer and all necessary measures have been taken to provide safe use of our product.

The self-certification of our product is done under Dutch law and with instructions of the Directive 89/686/EEC with due care to guarantee optimal use with the virus contamination risk mask product. Our product conforms with known standards and directives set for this product.

This PPE is in conformity with the the relevant Union Harmonisation Legislation Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standards No.

- EN 149:2001+A1:2009 *Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking*; Paragraph 7.9.2 Penetration of filter material
(See appendix A for test report, certificate no.: 140420DELE006)

Our conformity assessment procedure shall comply with all following categories:

- **Module A** – Internal production control.
- **Module B** – EC type-examination.
- **Module C** – Conformity to type based on internal production control
- **Module C2** – conformity to type based on internal production control plus supervised product checks at random intervals
- **Module D** - conformity to type based on quality assurance of the production process

Our Declaration of Conformity contains a full description of the product and the applied directives. The name and registration number of the Notified Body involved in certification procedures can be found on our website www.fpmask.com and comply with the requirements of an applicable 'harmonised standard,' which offer our conformity to the essential requirements. Harmonised standards can be identified by searching the 'Official Journal' on the European Commission's website, or by visiting the New Approach website established by the European Commission and EFTA with the European Standardisation Organisations.

Our technical documentation covers every aspect relating to conformity and includes all details of the design, development and manufacture of the product.

- Identification of the PPE concerned
- Technical description
- Drawings and photos
- Bill of materials
- Specification and EU declaration of conformity for the critical components and materials used
- Test reports and assessments on filter qualification
- Instructions

Our Technical documentation is available for 10 years after the delivery date of our product, and will stay available online.

The required information below is included in our data:

- Our name and production address.
- Details of the product (model, description and the serial number)
- List of applicable sectoral Directives and standards that have been applied
- A statement declaring that the product complies with all of the relevant requirements
- Signature, date and name of our CEO
- Details of the authorized representative within the EEA
- Our CE requirements are met for the product to be placed legally on the EEA market.
- Involved Notified Body

Disclaimer: Our masks are **not** intended for:

- medical use in Intensive care units or operating rooms.
- protection against gaseous fuels and fumes.
- Re-use protection against FFP1 directives small particles.
- Personal protective equipment against hazardous and gases

There are numerous 'Agreements on Mutual Recognition of Conformity Assessment' between the European Union and other countries such as the US, Japan, Canada, Australia, New Zealand and Israel. In those instances our CE mark is a Technical Conformity Mark.

Our product meets the essential Health and safety requirements from all the directives that applies to its product and we guarantee it meets all the tests, assessments and evaluation on the product to conform to all the requirements of *all* the directives that apply to the limited uses of our products.

The European Commission is aware that CE marking, like other certifications marks, is misused by many of our competitors. CE marking is sometimes affixed to products that do not fulfill the legal requirements and conditions.

Appendix A

Test report FP Mask filter according to EN 149:2001+A1:2009 *Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking*; Paragraph 7.9.2 Penetration of filter material

Filter penetratietest Mondkapjes (NEN-EN 149)



Certificaatnummer: 140420DELE006

Klant

Bedrijf : **Advise Mechanical Solutions**
Adres : **Witte Vlinderweg 6**
Postcode : **1521 PS**
Plaats : **Wormerveer**

Object

ID nummer : **TNE80**
Leverancier : **FP Mask**
Merk : **FP Mask**
Type : **Multi Layer System**
Klasse : **NA**

Wijze van onderzoek

De testen zijn uitgevoerd conform Kalibra protocol PR-VAL-017. Dit protocol is gebaseerd op de eisen overeenkomstig de NEN-EN149 en testmethodieken zoals omschreven in de NEN-EN 13274-7. Voor het uitvoeren van de metingen zijn zijn referentiestandaarden gebruikt zoals vermeld bij "Referentieapparatuur".

Testresultaten

De testresultaten zijn gegeven op de vervolgbladen.
Testresultaten worden getoetst tegen de eisen zoals gesteld in de NEN-EN 149.
De resultaten zeggen alleen iets over het rendement van de geteste maskers en geven geen garanties over de verdere functionaliteit van de maskers conform de norm.

Referentie apparatuur

Reg. Nr.	Omschrijving	Type	Cal. Datum	Geldig tot
X079-01	Aerosol generator	Topas 226	nvt	nvt
150702012	Deeltjesteller	Handheld 3016	1-apr-2020	1-mei-2021
130744019	Deeltjesteller	Handheld 3016	1-nov-2019	1-dec-2020
T95351537007	Anemometer	TSI 9535	19-okt-1905	1-nov-2020
70066	Drukmeter	Fluke 992	8-nov-2019	1-dec-2020

Uitvoering

Datum : **14-apr-2020**
Validatie technicus : **Dennis Leeuwenkuyl**
Resultaat : **Voldoet aan FFP1**

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Filter penetratietest Mondkapjes (NEN-EN 149)



Certificaatnummer: 140420DELE006

Samenvatting testresultaten

ID nummer : TNE80
Leverancier : FP Mask
Merk : FP Mask
Type : Multi Layer System
Klasse : NA

Voor het bepalen van de deeltjes penetratie van de mondmaskers zijn er testen uitgevoerd op 3 verschillende maskers. Per masker zijn er minimaal 5 metingen uitgevoerd. Onderstaand het gemiddelde van 5 metingen.

Klasse indeling conform de NEN-EN 149

Klasse : Rendement @ 95 l/min
FFP 1 : $\geq 80\%$
FFP 2 : $\geq 94\%$
FFP 3 : $\geq 99\%$

Test medium : NaCl
Flow : 32 l/min in de testopstelling met een oppervlakte snelheid van 0,11m/s (ca. 95 l/min over totale masker)

	Gemiddeld rendement voor deeltjes $\geq 0,3\mu\text{m}$	Conclusie (klasse)
Masker 1	84,90%	Voldoet aan P1
Masker 2	90,14%	Voldoet aan P1
Masker 3	90,07%	Voldoet aan P1

	Gemiddeld rendement voor deeltjes $\geq 0,5\mu\text{m}$	Conclusie (klasse)
	92,27%	Voldoet aan P1
	95,35%	Voldoet aan P2
	95,24%	Voldoet aan P2

Overall gemiddelde	88,37%	Voldoet aan P1
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	94,29%	Voldoet aan P2
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Overall conclusie:

Voldoet aan de eis van P1 (deeltjes van 0,3um)

Filter penetratietest Mondkapjes (NEN-EN 149)



Certificaatnummer: 140420DELE006

Meetresultaten

ID nummer : TNE80
Leverancier : FP Mask
Merk : FP Mask
Type : Multi Layer System
Klasse : NA

Masker	Meting	Deeltjesgrootte	Upstream	Downstream	Efficientie	Gemiddeld
1	1	≥ 0,3µm	269.162.382	40.850.593	84,8%	84,9%
	2		269.897.633	41.351.002	84,7%	
	3		271.745.297	40.880.963	85,0%	
	4		270.454.192	41.084.023	84,8%	
	5		271.028.762	39.961.723	85,3%	
	1	≥ 0,5µm	63.134.147	4.944.759	92,2%	92,3%
	2		63.129.556	4.926.749	92,2%	
	3		64.042.794	4.930.633	92,3%	
	4		63.590.766	4.930.633	92,2%	
	5		63.938.262	4.837.049	92,4%	
2	1	≥ 0,3µm	271.159.779	26.709.541	90,1%	90,1%
	2		273.064.652	26.689.765	90,2%	
	3		273.091.138	27.244.558	90,0%	
	4		275.276.057	27.273.869	90,1%	
	5		276.852.857	27.057.390	90,2%	
	1	≥ 0,5µm	63.843.619	2.971.729	95,3%	95,4%
	2		64.216.895	2.947.715	95,4%	
	3		65.183.810	3.069.550	95,3%	
	4		65.740.723	3.097.096	95,3%	
	5		65.847.726	3.017.991	95,4%	
3	1	≥ 0,3µm	275.920.549	26.662.219	90,3%	90,1%
	2		275.804.717	27.091.999	90,2%	
	3		275.254.880	27.402.768	90,0%	
	4		275.677.585	27.749.205	89,9%	
	5		273.448.523	27.770.394	89,8%	
	1	≥ 0,5µm	65.746.373	2.999.627	95,4%	95,2%
	2		65.997.813	3.079.085	95,3%	
	3		64.507.888	3.177.613	95,1%	
	4		65.535.544	3.140.180	95,2%	
	5		64.772.395	3.131.351	95,2%	

Weerstand over masker @ 95lpm *

Masker 1	22	Masker 2	22	Masker 3	22
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* de weerstand is gemeten bij een flow van ca. 30 lpm. Getest is over een oppervlak 44 cm². De gerapporteerde waarden zijn een factor 3 t.o.v. de gemeten waarden.

Filter penetratietest Mondkapjes (NEN-EN 149)

Certificaatnummer: 140420DELE006

Foto('s) van geteste maskers

