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Alpheios B.V. Attn. Mr. Coolen In de Cramer 8 A 6411 RS Heerlen Nederland

Subject: Your reference: Contact person: NaCl / Paraffin efficiency test on filtering face piece as agreed by email **M. de Jonge**

Dear Mr. Coolen,

At the request of Alpheios B.V. (your reference as agreed by email) ProQares performed particle efficiency experiments for Sodium chloride (NaCl) and Paraffin oil according to EN149 (2001 + A1 2009) to determine the classification of the material of a filtering face piece. The details of the received samples are presented in Table 1 and all test results are presented in Table 2 and 3. Note that the test results are only applicable to the tested materials, mentioned in Table 1. The samples arrived May 25th 2020, the experiments have been performed May 26th 2020.

Table 1: Received samples

Sample code ProQares	Description by customer
20 PQA 1061	Filtering face piece; Handanhy; FFP2 Flat Fold Particulate Respirator; Item HY9320; CE2797; EN149:2001 + A1:2009; FFP2 NR D; Manufacturer : Handan Hengyong Protective & Clean Products Co.,Ltd.

As agreed with VWS (April 3rd), the samples were tested as received only, also the duration has been shortened; similar as VG2 committee (EU Notified Bodies) consensus. Normally all experiments are conducted up to a total of 120 mg challenge aerosol, but in this report 3 are conducted for 30 minutes. The penetration procedure is following the BSI protocol, short certification procedure for the Corona crisis only, only applicable for respiratory protective devices for (para) medical personnel.

These changes from the standard are taken to speed up the possibility to introduce the samples to the medical personnel, which are in desperate need of the products during the Corona crisis, but still give ProQares sufficient confidence of the functionality of the material.

For FFP2 classification according to EN149, normally both NaCl and Paraffin oil should be conducted. In China to obtain KN95 classification only NaCl penetration is measured.

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The results of the solid aerosol (Sodium chloride / NaCl) and Paraffin oil according to Clause 7.19.2. are shown in Table 2 and 3.

Table 2: Filter penetration for Sodium chloride (NaCl)

Sample code	Penetration Sodium chloride (%)	Total loading (min)	
20 PQA 1061 – 1	0.2	30	
20 PQA 1061 – 2	0.7	30	
20 PQA 1061 – 3	0.7	30	
Requirement FFP1	<20%		
Requirement FFP2	<6.0%		
Requirement FFP3	<1.0%		

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Table 3: Filter penetration for Paraffin oil

Sample code	Penetration Paraffin oil (%)	Total loading (min)
20 PQA 1061 – 4	1.1	30
20 PQA 1061 – 5	1.1	30
20 PQA 1061 – 6	1.1	30
Requirement FFP1	<20%	
Requirement FFP2	<6.0%	
Requirement FFP3	<1.0%	

Overall conclusion: the filtering face piece meets the requirements for the particle efficiency regarding Sodium chloride in the as received state, to be classified as FFP3 according to requirements stated by EN149. With respect to Paraffin oil the filtering face piece meets the requirements for the particle efficiency to be classified as FFP2. Overall the classification can be classified as FFP2 for the penetration part of EN149.

This report is regarding the material penetration of the filtering face piece only, the protection of the total device is a combination of facial leakage and penetration of the material. In the circumstances we are living currently (COVID – 19) no Total Inward Leakage experiments are conducted in our laboratory.

The information above can be used by a specialist to decide whether the product could be used during the Covid-19 crisis as an appropriate protective device.

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Accuracy and Disclaimer

The breakthrough time of a filtering face piece in case of an adsorption experiment depends on the following parameters:

- the air flow through the filtering face piece
- the influent concentration
- the temperature
- the relative humidity of the air
- the effluent concentration

When all uncertainties of the parameters are taken into account, the accuracy of the breakthrough time is determined to be \pm 10%.

It should be noted that the above values have not been taken into account when making the assessment. The results that are reported in this document concern the samples with internal ProQares sample code 20 PQA 1061 only. The results do not necessary hold for other samples of the same type.

In case of public communication about the results please mention that the tests have been conducted by ProQares B.V. as the testing agency.

We trust all things are clear to you. In case of any questions, please do not hesitate to contact us.

Kind regards,

M. de Jonge Author

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