



Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200316-055-FPC A

Certificate holder:	Guangzhou Powecom Labor Insurance Supplies Co., Ltd. Floor 1, 3 and 4, Building 1, No.43, Tuanjie Road, Xinya Street, Huadu District, Guangzhou City, Guangdong Province, P.R. China
The scope of the certification for:	The manufacture of respiratory protective device See annex for articles covered by this certificate
Validity from:	2020-04-28
To:	2021-04-27

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation. The equipment covered by this certificate is listed in the accompanying schedule. This certificate is not complete and has no validity without the accompanying schedule and revision index. The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE mentioned in the schedule which accompanies this certificate whilst this certificate remains valid. This certificate and the accompanying schedule remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



Approved by Ireland
Government
as a Notified Body
for CE Marking No.2834



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15,
D15 AKK1, Ireland

Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Schedule of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

Schedule to CCQS FPC Certificate No.: CE-PC-200316-055-FPC-A

Product reference and description		Reference standard
Particle filtering half masks	Model: 9502	EN 149:2001 + A1:2009
Certificate Revision.	Revision details	Revision date
A	Initial issue	2020-04-28



This schedule has no validity without the accompanying certificate.

This schedule and the accompanying certificate remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

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NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangzhou Baoweikang (Powecom) Personal Protection Equipment Co., Ltd.

Model Tested: KN95 Protective Mask

Date Tested: April 22, 2020

These findings pertain to the Guangzhou Baoweikang (Powecom) Personal Protection Equipment Co., Ltd., KN95 Protective Mask. The labeling for this product indicates that it meets GB2626-2006 KN95, the Chinese standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking.

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found [here](#).

A certificate of approval was provided with the samples received; however, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 99.40% and 99.21%, respectively. All of the respirators measured more than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirator's represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for [Crisis Capacity Strategies \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: April 22, 2020

Report Prepared: April 23, 2020

Manufacturer: Guangzhou Baoweikang (Powecom) Personal Protection Equipment Co., Ltd.

Item Tested: KN95 Protective Mask

Country of Certification: China (GB2626-2006 KN95)

Pictures have been added to the
end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	8.5	0.545	0.688	99.31
2	85	8.5	0.626	0.793	99.21
3	85	9.0	0.509	0.659	99.34
4	85	8.5	0.542	0.721	99.28
5	85	8.6	0.497	0.637	99.36
6	85	8.4	0.495	0.674	99.33
7	85	8.4	0.560	0.745	99.26
8	85	8.3	0.594	0.759	99.24
9	85	8.8	0.472	0.604	99.40
10	85	8.5	0.568	0.745	99.26
Minimum Filter Efficiency: 99.21			Maximum Filter Efficiency: 99.40		

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.

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