



Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200722-565-01-9A

Certificate holder:	Changzhou Huankang Medical Device Co., Ltd. No.22, Changhe Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China
Product:	Particle Filtering Half Mask Detailed product description listed in the Annex
Model(s):	HK-Z03
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-08-27
Revision date:	2020-08-27
Expiry date:	2021-08-26

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.

Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.

CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.

If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.

This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.



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



CCQS Certification Services Limited

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D15 AKK1, Ireland

Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie

If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200722-565-01-9A

Applicable standards and specification:

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Model reference	Product description
HK-Z03	Folding filtering half mask fitted with head harness clip, no valves, internal metal nose clip Mask body color: White Classification: FFP2 NR Test report No.: 2020(F) - 0431

Certificate Revision	Revision date	Revision details
A	2020-08-27	Initial issue



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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-200722-565-FPC-A

Certificate holder:	Changzhou Huankang Medical Device Co., Ltd. No.22, Changhe Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China
Manufacturing location:	No.22, Changhe Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China
The scope of the certification for:	The manufacture of respiratory protective device See annex for articles covered by this certificate
Validity from:	2020-08-27
Revision date:	2020-08-27
To:	2021-08-26

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.



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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-200722-565-FPC-A

Product reference and description		Reference standard
Particle Filtering Half Mask	Model: HK-Z03	EN 149:2001+A1:2009

Certificate Revision	Revision date	Revision details
A	2020-08-27	Initial issue

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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