



Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200402-191-01-9B

Certificate holder: **Carte Medical Equipment (Suzhou) Co., Ltd.**
No.1978, Fenhui National Road, Wujiang City, Suzhou City, Jiangsu Province, China

Product: **Particle Filtering Half Mask**
Detailed product description listed in the Annex

Model(s): K8201

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

Issue date: 2020-05-29

Revision date: 2020-08-01

Expiry date: 2021-05-28

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This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.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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If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



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Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200402-191-01-9B

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
K8201	Folding filtering half mask fitted with ear loops with head harness clip, no valve, internal metal nose clip Classification: FFP2 NR Test report No.: 2020(D) - 0291

Certificate Revision	Revision date	Revision details
A	2020-05-29	Initial issue
B	2020-08-01	Certificate validity extended to one year



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