



EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

White folder half mask with out valve



CCQS Certification Services Limited. (NB 2834) performed the EU Type Examination (Module B) and issued the Type

Examination Certificate Number:

No.	EU Type Examination (Module B) Certificate Number
1	CE - PC - 200402 - 191 - 01 - 9B

Product Category:

- ☐ This product is Category II.
- ☒ This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB2834)

Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
Particle Filtering half mask	K8201	FFP2	A200901

The Manufacturer's name and address is as follows:

Name:	Carte Medical Equipment (Suzhou) Co., Ltd.
Address:	No.1578, Fenhuan Road, Wujiang City, Suzhou City, Jiangsu Province, China

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer. Detailed description of the PPE to allow traceability/identification of the PPE.
Model : K8201
FFP2 NR

The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149: 2001+A1: 2009

- ☐ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB2834)

Signature: Jasmine Date: 2020.9.01

Company stamp and/or legal signature: Chang-Lin