

# EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

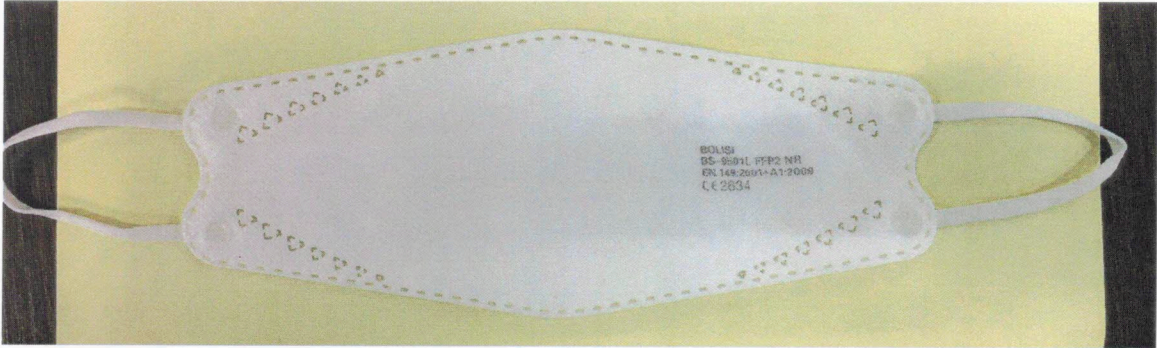

Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
Particle filtering half mask	BS-9501L	FFP2 NR	
Particle filtering half mask	BS-9501FL	FFP2 NR	
Particle filtering half mask	BS-9502C	FFP2 NR	
Particle filtering half mask	BS-9502FC	FFP2 NR	

The Manufacturer 's name and address is as follows:

Name:	Suzhou Bolisi Medical Technology Co., Ltd.
Address:	Baijiqiao industrial community, Yangshe Town, Zhangjiagang City, Jiangsu Province, P.R. 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.

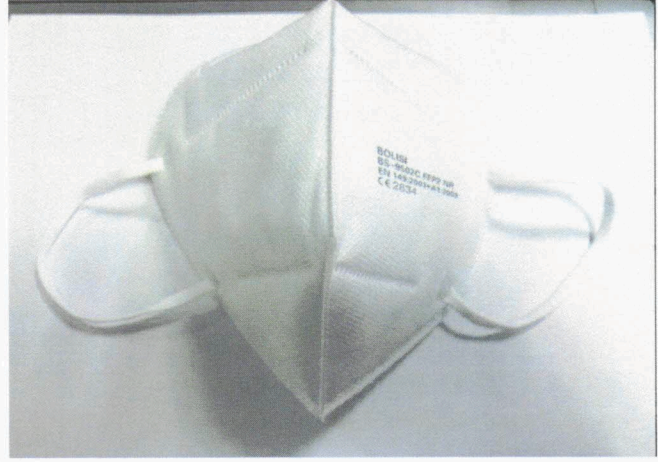
BS-9501L	White folder half mask without valve 
BS-9501FL	White folder half mask with exhalation valve. 





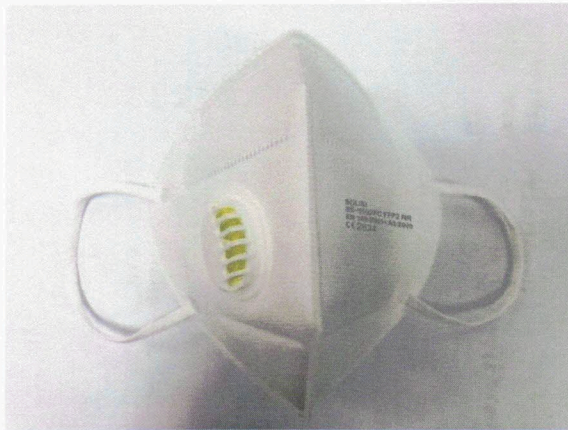
BS-9502C

White folder half mask without valve



BS-9502FC

White folder half mask with exhalation valve.



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

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-200313-045-01-9B

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. (NB 2834)
- 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. (NB 2834)

Signature :  Date : 2020. 4. 10 Company stamp and/or legal signature : 

