

江苏常美医疗器械有限公司

Jiangsu Changmei Medtech Co., Ltd.

EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

The basic information is as follows:

1. The base morniador is as follows.				
Product Name	Model	Classification/Type	Batch No./Serial No./Identifier	
Particle filtering half mask	DFM-01	FFP2 NR	DFM20110201	

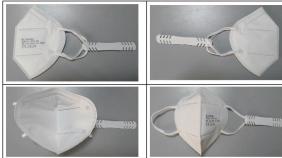
. The Manufacturer 's name and address is as follows:

Name:	Jiangsu Changmei Medtech Co., Ltd.
Address:	No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China

- 3. This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.
- 4. Detailed description of the PPE to allow traceability/identification of the PPE.

Model: DFM-01 FFP2 NR

White folder half mask without 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		

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

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No.	EU Type Examination (Module B) Certificate Number	
1	CE-PC-200330-138-01-9B	

- 8. Product Category:
 - □ This product is Category II.
- This product is Category III and is subject to Module C2 internal production cortrol plus supervised product checks at random intervals and is under the surveillance of CCCC Certification Services Limited. (NB 2834)
- This product is Category III and is subject to Module of Conformity to type based on quality assurance of the production process and is under the surveillance of CQS Certification Services Limited. (NB 2534)

Signature: Date: 2020.11.02

Company stamp and/or legal signature:

Date: 2020.11.02