



UNIVERSAL
CERTIFICATION

NB 2163

CONFORMITY TO TYPE CERTIFICATE

Certificate No: 2163-PPE-684/02

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Shandong Zeda Medical Products Co., Ltd.

Yaojia Village, Zaoyuan Town, Lanshan District, Linyi City, Shandong Province, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial Nr.	Date	Issuing NB Nr.
SIJIJE / K1210	FFP2 NR	2163-PPE-684/R1	28.05.2021	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **28/05/2021** and will be valid for one year, until **27/05/2022** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director





DECLARATION UE DE CONFORMITE

Equipement de protection respiratoire

Masque FFP2

CAMERON MEDICAL SAS, dont le siège social est 12 rue Charles Infroit, 92 190 Meudon, déclare sous sa seule responsabilité que l'équipement de protection individuelle neuf décrit ci-après :

- Masque FFP2, non stérile à usage unique
- Classe : P2
- Référence : CAMED-50-P2ST
- Usine : ZEDA
- Modèle : K1210

Ces produits répondent aux exigences de la directive européenne relative aux équipements de protection individuelle EU 2016/425 Annexe 9 et ont été testés conformément à la norme 149:2001 + A1:2009 par l'organisme notifié par la Commission Européenne : UNIVERSAL CERTIFICATION et dont le numéro d'accréditation CE est le : NB 2163.

Les performances constatées par l'organisme notifié UNIVERSAL CERTIFICATION lors du test à la norme EN 149:2001 + A1:2009 sont présentées dans la fiche technique Cameron Medical et reprennent les résultats du Technical Assessment report n°: 2163-KKD-684

Fabriqué en Chine dans l'usine : Shandong Zeda Medical Products Co., Ltd. certifiée selon ISO9001:2008, ISO 14001:2004 et OHSAS 18001:2007.

Meudon,
Le 07/07/2021

Adrien Sandrini
Président

**Adrien
Sandrini**  Signature numérique
de Adrien Sandrini
Date : 2021.07.07
11:17:34 +02'00'

