



EC DECLARATION OF CONFORMITY



1. The name and address of factory/applicant:

Zhejiang Langci Medical Equipment Co., Ltd.

Building No. 2, Chengnan Industrial Park, Meicheng, Jiande 311600, Zhejiang Province, China

2. The name and address of the authorized person to prepare the technical documents:

Jianxiong Liu

Building No. 2, Chengnan Industrial Park, Meicheng, Jiande 311600, Zhejiang Province, China

3. Description of the product:

Name: FFP2 NON-POWERED AIR-PURIFYING PARTICLE RESPIRATOR

Model: 5001

4. Declaration of the factory:

The above-mentioned manufacturer declares that the machine conforms to the requirements as the following directives:

EC Directive applied: Personal Protective Equipment Regulation (EU) 2016/425 Annex 9

5. Harmonized standard applied:

Harmonized standard applied: EN 149:2001 + A1:2009 FFP2 NR

EC Type Certificate Issuing NB No: 2163

EC Type Certificate No: 2163-PPE-726/01

6. Identification of subscriber:

surname and family name: Jianxiong Liu

position: Building No. 2, Chengnan Industrial Park, Meicheng Town, Jiande City
311600, Zhejiang Province, P. R. China

location and date: Zhejiang China, 2020.7.12

signature:

EC prohlášení o shodě

1. Jméno a adresa výrobce/žadatele:

Zhejiang Langci Medical Equipment Co.,Ltd

Building No.2, Chengnan Industrial Park, Meicheng, Jiande 311600, Zhejiang Province, China

2. Jméno a adresa oprávněného k přípravě technické dokumentace:

Jianxiong Liu

Building No. 2, Chengnan Industrial Park, Meicheng, Jiande 311600, Zhejiang Province , China

3. Popis produktu:

Název: FFP2 respirátor bez výdechového ventilu

Model: 5001

4. Prohlášení výrobce:

Výše uvedený výrobce prohlašuje, že výrobek splňuje požadavky následujících směrnic

Použitá směrnice ES: Nařízení o osobních ochranných prostředcích (EU) 2016/425, příloha 9

5. Použití harmonizované normy:

Harmonizovaná norma: EN 149:2001 + A1:2009 FFP2 NR

Vydání certifikátu typu NB č.: 2163

Certifikát typu EC č.: 2163-PPE-726/01

6. Identifikace účastníka (níže podepsaného):

Rodné jméno a příjmení: Jianxiong Liu

Adresa: Building No. 2, Chengnan Industrial Park, Meicheng, Jiande 311600, Zhejiang Province , P.R. China

Místo a datum: Zhejiang China, 2020.7.12

Podpis:



UNIVERSAL CERTIFICATION

NB 2163

UNIVERSAL CERTIFICATION

Certificate No: 2163-PPE-726/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by
Zhejiang Langei Medical Equipment Co., Ltd.
Building No. 2, Chengnan Industrial Park, Meicheng Town, Jiande City 311600, Zhejiang
Province, P. R. 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 149:2001 + A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VI (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 No	Date	Issuing NB No
LANGEI 5001	FFP2 NR	2163-PPE-726	09.06.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and em (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 22/07/2020 and will be valid for one year, until 21/07/2021 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.



ŞİMİ KAÇMAZ
UNIVERSAL CERTİFİKASYON
Director

Verify this validity with the QR code

