

# UNIVERSAL

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UNIVERSAL  
CERTIFICATION

NB 2163

## EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 685

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

**CHENGDE TECHNOLOGY CO. LTD.**

No.888-1088 Shiji Ave., Longgang City, Zhejiang Province, China

are tested and evaluated according to

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

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

### Product Definition

Model: CD9501

Filtering half mask

Total Inwards Leakage: Class – FFP2 NR

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.**
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **21 / 05 /2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE  
2163

Suat KACMAZ

UNIVERSAL CERTIFICATION  
Director



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CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-685/01

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

**CHENGDE TECHNOLOGY CO. LTD.**

No.888-1088 Shiji Ave., Longgang City, Zhejiang 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 No	Date	Issuing NB No
CD9501	FFP2	2163-PPE-685	21.05.2020	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 **08/06/2020** and will be valid for one year, until **07/06/2021** 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.



Suat KACMAZ  
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Director

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Date: 07.05.2020

Confirmation Letter,

**Manufacturer** CHENGDE TECHNOLOGY CO., LTD  
**Address** No.888-1088 Shiji Ave., Longgang City, Zhejiang Province  
**Contract No** CE-PPE-2220  
**Contract Date** 07.05.2020

To whom it may concern,

This letter is to confirm that *Chengde Technology Co., Ltd.* Company Address: *No.888-1088 Shiji Ave., Longgang City, Zhejiang Province* has entered into the service agreement *CE-PPE-2220* with UNIVERSAL CERTIFICATION with regards to the application of Module B EU Type Examination Certification and Module C2 production monitoring for Particle filtering half masks, Model: *CD9501* within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III.

In case of any doubt about the integrity of this letter, please contact UNIVERSAL CERTIFICATION by email ([info@universalcert.com](mailto:info@universalcert.com)) to verify.

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Necip Fazıl Bulvarı, Keşap Sitesi, E2 Blok, No:44/84  
Yukarı Dudullu-Ümraniye/İSTANBUL  
Telefon: 0216 455 80 80 Faks: 0216 455 80 08  
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VE GÖZETİM HİZM.  
TİC. LTD. ŞTİ.

Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director



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商会会刊

企业风采

	ORICH Medical Equipment (Nanjing) Co.,Ltd.		
206	诚德科技股份有限公司 Chengde Technology Co.,Ltd	91330300145793048G	欧盟CE
207	金华家大夫医用品有限公司 Jinhua Jiadaifu Medical Supplies co., LTD	91330702MA2HQDMDXN	欧盟CE
208	浙江衢州荣博医疗器材有限公司 Zhejiang Quzhou Rongbo Medical Instrument Co.,Ltd.	913308007625355461	欧盟CE
209	浙江衢州荣博医疗器材有限公司 Zhejiang Quzhou Rongbo Medical Instrument Co.,Ltd.	913308007625355461	德国EUA
210	浙江蓝禾医用品有限公司 Zhejiang Lanhine Medical Products LTD.	91330282099396171A	欧盟CE
211	宁波伊夫路讯防火设备有限公司 Ningbo Evolution Fire Safety Equipment Co.,Ltd	91330281MA281R3F9M	欧盟CE
212	浙江璐瑶电子科技有限公司 Zhejiang Luyao Electronics Technology Co.,Ltd.	91330326726586004L	欧盟CE
213	浙江壹可生物科技有限公司 Zhejiang Yike Biotechnology Co., Ltd.	91330201MA2H45KRXT	德国EUA
214	浙江利济医疗科技有限公司 Zhejiang Liji Medical Technology Co., Ltd.	91330881MA2DJ0PL71	德国EUA

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