FFP2 CE ---NB2163

LEIKANG

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CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-KKD-972

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

Wenzhou Leikang Medical Technology Co., Ltd.
Room 401, 4th floor, Building No. 21, Wenzhou National University Science Park, No. 89 Fengfang Rd. Economic Development Zone, Ouhai District, Wenzhou, 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

Brand Name: LEIKANG **Model:** LK-008
Filtering half mask
Classification: 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 **07/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

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Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE–972/01

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

Wenzhou Leikang Medical Technology Co., Ltd.
Room 401, 4th floor, Building No. 21, Wenzhou National University Science Park, No. 89 Fengfang Rd. Economic Development Zone, Ouhai District, Wenzhou, 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
LEIKANG / LK-008	FFP2 NR	2163-PPE–972	07.07.2020	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 **07/07/2020** and will be valid for one year, until **06/07/2021** 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.

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Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 07.07.2020 / 2163- KKD-972

Manufacturer: Wenzhou Leikang Medical Technology Co., Ltd.
Address: Room 401, 4th floor, Building No. 21, Wenzhou National University Science Park, No. 89 Fengfang Rd. Economic Development Zone, Ouhai District, Wenzhou, Zhejiang Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Trust Right Testing and Certification Service (Zhongshan) Ltd. accredited by IAS (International Accreditation Service), signatory to ILAC MRA, with number TL-861 for the product identified below, dated 12.06.2020 with Serial No R20200049 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 01 July 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask
Classification: FFP2 NR
Trademark: LEIKANG **Model:** LK-008

UFR-383 12.12.2018 Rev.01

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