



UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1090

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

Zhuhai IVI Healthcare Medical Device Co., Ltd.

No.1, 4th floor, 2nd phase, Nanping Technology industrial park, No.8, Pingbei 2nd Rd,
Xiangzhou, District, Zhuhai, Guangdong, China 519060

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: IOB **Model:** ivi N9501

Filtering half mask

Classification: FFP3 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 **19/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KACMAZ
UNIVERSAL CERTIFICATION
Director

