

Basic Information of manufacturer, EU Representative

Device: SARS-CoV-2 IgG/IgM Rapid Test

Manufacturer Zuhai Encode Medical Engineering Co., Ltd

Drafted by: Xiongwei Date: 2020.2.13

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1 Information of manufacturer

1.1 Company profile

Founded in 1994, as one of China's earliest developed enterprises in the circle of microbiological in vitro diagnostic reagents, Encode Medical Engineering Co., Ltd integrates research, production and sales and is running on a larger scale. Since the very beginning, Encode is consistently engaged in research and development of in-vitro diagnostic reagents. So far we have researched and developed series of microbiological and immunology reagents, which are used for laboratory diagnosis of mycoplasma, chlamydia, pneumonia, pathogenic fungus, tuberculosis, bacterial vaginosis, neisseria gonorrhoeae, etc. The sales network has covered all over the country.

In 2005, we constructed our study, research & manufacturing base in Zhuhai, a predominant city of biotech industry in south China, which covers 15,000m². The base installed with automatic manufacturing lines including freeze-dry line and over 2,000m² standard GMP air-purified workshops makes it definite for company to develop or larger scale, and with more intensive manufacturing and high technology.

We obtained ISO9001 & ISO13485 (Especially in Medical Device Manufacture Management) quality management system verification in 2006. From 2007 to 2009, after the new in-vitro diagnostic reagents regulations were issued, we successionaly passed the rigorous quality management system evaluation organized by SFDA and GDFDA. And we also got class 3 certificates for our main products—Mycoplasma Susceptibility Test Kit, Fungi Susceptibility Test Kit, *Chlamydia Trachomatis* Antigen Testing Kit (Colloidal Gold) and *M. tuberculosis* Antibody (IgG) Testing Kit (Colloidal Gold).

Under “industry-study-research” collaboration mode, Encode has established extensive cooperative ties with Lanzhou University, South China University of Technology and Jinan University and has become teaching and practice base of College of Life Science, Lanzhou University, South China University of Technology and Zhuhai Health School. Encode enjoys a high reputation in this field and has been rated as one of Guangdong high-tech enterprises and national high-tech enterprises.

Our president Steven Sun was elected as vice-chairman of CACLP and employed as an adjunct Professor of College of Life Sciences, Lanzhou University in 2008.

The R&D (research and development) center, directly led by the general manager, with numbers of experts and technicians on different levels, covers various fields. We are keeping innovating and improving based on feedbacks from market. We are also continuously investing in research, developing application scope & technology level of in-vitro diagnostic reagent in microbiology, immunology and molecular biology. With financial support from governments at different levels we have undertaken four research items (in process) and have been granted the title of national high-tech enterprise.

Sincerity and harmony are our faith; quality and efficiency are our targets. Relying on our scientific management, mature marketing strategy, years of manufacturing experience, good enterprise image and popular brand, we believe that we will provide you with the most professional service.

1.2Contact

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2 Information of EU representative

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