

Medical Device Quality Management System Certification

Registration No.: 46821YL0001R0S

This is to certify

Changsha Renji Medical Equipment Co., Ltd.

Organization Code: 91430181MA4RPFWQ23 Registration Address: Building B8, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, Hunan Province, China

> In conformity with YY/T 0287-2017 idt ISO 13485: 2016

Certification scope

Production of Disposable Virus Specimen Collection Tube, Disposable Sampling Swab, Viral RNA&DNA Extraction Kit, Novel Coronavirus (COVID-19) Nucleic Acid Detection Kit (Real-time RT-PCR Method), SARS-CoV-2 (COVID-19) Antigen Rapid Test Kit(Colloidal Gold), SARS-CoV-2 (COVID-19) Neutralizing Antibody Rapid Test Kit(Colloidal Gold) and Blood Collection Tube within the scope of qualification.

Issue Date: Feb 03, 2021 Expiry Date: Feb 02, 2024 Date of Renewal: Sept 18, 2021

Authorized by



After this certificate is issued, there should be at least two surveillance audits within the validity period of 3 years. The validity of the certificate can be checked at www.ybtc. org.cn. The certification information is available on the official website of the National Certification and Accreditation Administration (www.cnca.gov.cn). It is also available by scanning the QR codein the lower right.



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