

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 Date of Renewal:

Expiry Date: Feb 02, 2024

Authorized by



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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.

Address: No.61 Jinma Road, Furong North Road, Kaifu District, Changsha City, Hunan

