

Certificate of FDA Registration

Cert. No. 2024MD0131PR03

This is certificated that

Registration number:3016919945

Shanghai Gene Era Bio-Science Co.,Ltd.

No.211 East Huancheng Road, Fengxian, Shanghai, 201400, China

Owner Number: 10066778

Status: Active

Date of Registration status: 2024

Device Listing Number:

| Listing Number | Product code(s) | Device class | Device Name(s) | Proprietary Name |
|-------------------|-----------------|---------------------|--|--|
| D467181 | JQC | I | CENTRUFUGES(MICRO, ULTRA, REFRIGERATED) FOR CLINICAL USE | GEB Centrifuge tube,GEB Plastic pipette tips, GEB PCR series |
| D467180 | LXG | 1 | EQUIPMENT,LABORATORY,GENERAL PURPOSE, LABELLE OR PROMOTED FOR A SPECIFIC MEDICAL USE | GEB PCR Series (2D Code tube/plastic pippette tips/test tube/tube racks) |
| D494203 | JRA | 1 | MICROTITRATOR, FOR CLINICAL USE | 1 |
| D494204 | BYG | I | MASK,OXYGEN | Oxygen mask |
| D530237 | PPM | ı | GERNERAL PURPOSE REAGENT | Nucleic acid Pretreatment reagent |
| D384623 | LYU | 1 | ACCESSORY, SURGICAL APPAREL | 1 |
| D384624 | OEA | 1 | NON-SURGICAL GOWN | Non-surgical gown |
| D384625 | HOY | I | SHIELD, EYE, OPHTHALMIC (INCLUDING SUNLAMP PROTECTIVE EYEWEAR AND POST-MYDRIATIC EYEWEAR) | Eye shield |

Was registered with US Food & Drug Administration, Center for Device and Radiological Health, pursuant to 21 CFR 807.

Date of issue: 31.01.2024 Valid Date: 31.12.2024



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