



CE Technical Documentation Review Report

Regulation EU 2017/745

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| Applicant: | Kangou Anlu Group Medical Device Co., Ltd (Shanghai) Co., Ltd. Address: Shanghai, China |
| Report Number: | ISCR7452020B9J7I |
| Examination Intent: | Examination the completeness of the Technical Documentation according to the requirements of the Annex II, Annex III of EU 2017/745(MDR). |
| Product(s): | Disposable Face Mask |
| Type(s)/Models: | 175mm x 95mm |
| Standard(s): | EN 14683:2019 |
| Classification: | Class I (according to annex VIII of Regulation EU 2017/745(MDR)) |
| Examination period: | March.31.2020 |
| Date of expiry: | March.30.2021 |
| Review result: | During the examination of the provided Technical Documentation, No non-compliance was detected according to the requirements of the Medical Devices Regulation EU 2017/745 Annex II, Annex III. |

International Standards Certification Ltd.

Manager: Autumn Shen

Email: info@accreditservice.com

Date: March 31, 2020

For and on behalf of
INTERNATIONAL STANDARDS CERTIFICATION LIMITED
國際標準認證有限公司

Autumn Shen
Authorized Signature(s)



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