



Fiscal Year 2020 USA FDA CERTIFICATION OF REGISTRATION

This certifies that:

Guangdong Meibao Cosmetics Co., Ltd.
Beihuan South Road Industrial Estate, Xiashan Chaonan District, Shantou,
Guangdong, 515144, China

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

MicroKy Services, LLC.

Owner/Operator Number: 10063229

Device Listings:

Listing Number	Product Code	Device Name ➤ Proprietary Name	Premarket Submission Type
D375761	MSH	RESPIRATOR, SURGICAL ➤ Disposable Medical Mask: 182mm*114mm, 175mm*95mm, 180mm*104mm	510(k) Exempt
D375763	KHA	MASK, SCAVENGING ➤ Disposable Mask: 182mm*114mm, 175mm*95mm, 180mm*104mm	510(k) Exempt
D375766	LRJ	DISINFECTANT, MEDICAL DEVICES ➤ Alcohol Spray: 100ml ➤ Alcohol Gel: 100ml, 400ml	510(k) Exempt

MicroKy Services, LLC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. MicroKy Services, LLC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. MicroKy Services, LLC assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, MicroKy Services, LLC is not affiliated with the U.S. Food and Drug Administration.



MicroKy Services, LLC



Executive Director
Issued: Mar. 19, 2020
Cert. No.: 2020031901
Expiration Date: Dec. 31, 2020

CE Documentation Review



No. 3J200321.GDMUO49

Holder: **GUANG DONG MEIBAO COSMETICS CO., LTD.**

Beihuan South Road Industrial Estate, Xiashan Chaonan District, Shantou City, Guangdong

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable medical mask, Disposable mask (Not Sterile)

Model(s): 182*114mm, 175mm*95mm, 180mm*104mm

Classification: Class I (Not Sterile)
(accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 21 March 2020

Approver

ECM Service Director
Luca Bedonni



Expiry date 20 March 2025

Technical Expert
Amanda Ferrero



Ente Certificazione Macchine