

CE Documentation Review



No. 3J200312.LSM0U007

Holder: Luohe Shunkang Medical Supplies Co., Ltd.
Yancheng District Xiandian Town Yanxiang Road ,
Luohe City, Henan Province

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Medical Mask

Model(s): Three layer sterile ear type, tether type
175mmx90mm, 175x95mm, 140mmx90mm

Classification: Class II
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 12 March 2020

Expiry date 11 March 2025

Service Manager
Luca Bedonni

Deputy Manager
Amanda Pini

Ente Certificazione Macchine

Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy



Fiscal Year 2020 USA FDA CERTIFICATION OF REGISTRATION

This certifies that:

Luohe Shunkang Medical Supplies Co., LTD.
Yanxiang Road, Xindian Town, Yancheng District, Luohe,
Henan, 462342, 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: 10062906

Device Listings:

| Listing Number | Product Code | Device Name ➤ Proprietary Name | Premarket Submission Type |
|----------------|--------------|---|---------------------------|
| D374773 | MSH | RESPIRATOR, SURGICAL ➤ Disposable Medical Mask: Three Layers of Sterile Hanging Ears, 175mm*90mm, 175mm*95mm, 140mm*90mm ➤ Medical Mask: Three Layers of Sterile Hanging Ears, 175mm*90mm, 175mm*95mm, 140mm*90mm | 510(k) Exempt |
| D374774 | KHA | MASK, SCAVENGING ➤ General Purpose N95 Mask: Cup Cover, Foldable, 140mm*140mm | 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 noted 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

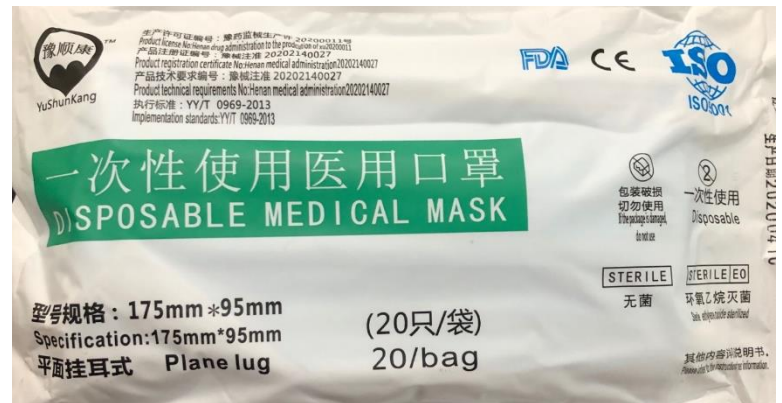


Executive Director
Issued: Mar. 18, 2020
Cert. No.: 2020031803
Expiration Date: Dec. 31, 2020

3 Ply Surgical Masks

EO Sterile

FDA and CE Approved



175mm by 95mm

20 masks in a bag