



CERTIFICATE OF FDA REGISTRATION

Certification No.: CTCSD2020272

Dear Official Correspondent:

This document provides notification of the registration number assigned to your establishment:

Establishment:

Address:

Owner/operator NO.: 10062858

Listing Number	Premarket Submission Number	Product Code(s)	Device Name	Activities
D374583	EXEMPT	KHA	MASK, SCAVENGING	Manufacturer

General Manager
CTC REGISTRATION LLC
Email: ctc-086@hotmail.com
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Validity: Dec.31,2020

Conclusion:

This certificate makes no other representations or warranties, nor does it make any representations and warranties to any person or entity other than the named certificate holder. CTC assumes no liability to any person or entity in connection with the foregoing. 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. CTC is not affiliated with the U.S. Food and Drug Administration.

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Certificate Number **UCN** : **802730433111**
Job : J29243
Date of Issue : 2020-03-18
Certificate valid up to : 2024-03-17

Brand Name : See Label
Type : Disposable Mask
Model N : ear hanging type ,flat shape, duck bill shape, arch shape, folding type

Manufacturer
Address


Standard Used : EN 14683:2005

Conclusion :

After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .

The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : TMZJ20031122168	✓ OK
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

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General Manager – CELAB


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