



The 3rd Party Certificate of
FDA Medical Device Registration

Note:

This file is Not being issued by FDA. We, SFT, as the 3rd party, produce it, intended to facilitate customer display & transmit information. The following contents, FDA registered Facility/Owner/Operator&FDA listing Medical Device, are excerpted from database at www.fda.gov.

Establishment:

[DONGGUAN HUAGANG COMMUNICATION TECHNOLOGY CO., LTD.](#)

No.78 jinheRoad,jinmei Village,Changping Town Dongguan Guangdong,
CHINA 523579

Registration Number / FEI Number*:

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Status: **Active**

Date of Registration Status: 2020

Owner/Operator

[DONGGUAN HUAGANG COMMUNICATION TECHNOLOGY CO., LTD.](#)

No.78 jinheRoad,jinmei Village,Changping Town Dongguan Guangdong,
CHINA 523579

Owner/Operator Number: [10062778](#)

Official Correspondent

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Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable Face Mask	LYU	1	D373853	Manufacturer
Disposable Face Mask	OEA	1	D373854	Manufacturer

Please careful protect your Listing Number.

Professional FDA Registration Services, by Shanghai Shifu Testing Service Co., Ltd.

More details on the website: <http://www.sft-lab.com>.

Need help? Contact us, SFT, at +86(021) 51300821&sales@sft-lab.com.cn

FDA CERTIFICATE NUM: [SFT20MAR006C](#)

Certificate of Compliance



No. 0P200310.DHC0W93

Technical Construction File no. TPGD20030521963

Certificate's
Holder:

Dongguan HuaGang Communication
Technology Co., Ltd.
No.78 Jinheroad, Jinmei Village, Changping Town,
Dongguan City, Guangdong, China.

Certification ECM
Mark:



Product:
Model(s):

Disposable Face Mask
KN95-A KN95-B (Class of device: FFP2 NR D)

Verification to:

Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it.
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the **CE** Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the **CE** Mark on the product(s).

Date of issue 10 March 2020

Expiry date 09 March 2025

Chief Manager
Marco Morino

Deputy Manager
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