

Disposable Medical Mask



FDA-Class 2

FDA-二类



Certificate of Medical Device Registration

This certifies that:

jinhua, ZHEJIANG, 321000, CHINA

Is registered with U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Title 21 CFR Part 807, such registration having been verified as currently effective on the date hereof by Canning-tech. This certificate makes no other representations or warranties, nor does it make any representations or warranties to any person or entity.



Device Listing: D375547 LYU ACCESSORY,SURGICAL APPAREL

D378147 MSH Respirator,surgical

Certificate Expires: Dec. 31, 2020

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Maria Sun
Executive Director
HZ Canning Sci. & Tech. Co., Ltd
Date: 03-25-2020



CE-MDD

CE-医疗器械类

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CERTIFICATE

Certificate Number UCN : 802802049276
 Job : J29239
 Date of Issue : 2020-03-26
 Certificate valid up to : 2024-03-25
 Brand Name : DR family
 Type : single-use medical face mask
 Model N : Hanging ear type

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 : MTCF0314-MDD	✓ OK
Presence of CE 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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Massimiliano Bertoldi
General Manager - CELAB
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Product Detail

产品详情

Three layers of protection

三层防护

外层无纺布

隔绝飞沫等可见物

Non-woven fabric

Isolate visible objects such as droplets

中层熔喷布

过滤空气中非油性颗粒

Middle meltblown cloth

Filter non-oily particles in the air

内层无纺布

舒适亲肤 干爽透气

Non-woven fabric

Comfortable and skin-friendly



Product Detail

产品详情

贴合面部曲线、有效隔离、舒适透气

Fits to the curve of the face, effectively isolates, and is comfortable and breathable





Environment and equipment

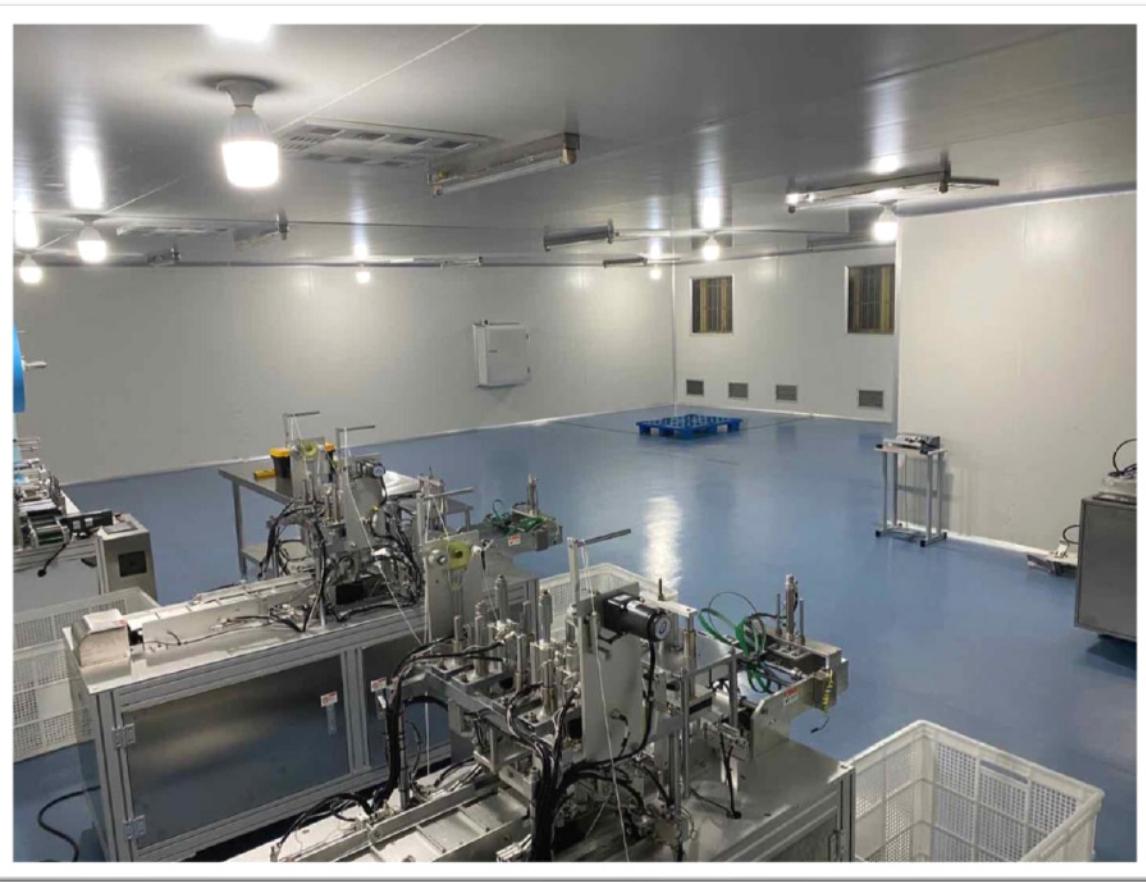
生产环境及设备





Environment and equipment

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