



First Pro

FICHA TÉCNICA

Mascarilla 3 pliegues Mayfields



DESCRIPCIÓN

Mascarilla quirúrgica 3 capas 3 pliegues. Protección BFE-VFE-PFE mayor/igual a 95%. Cada mascarilla en bolsa individual. Capa exterior color celeste.

DESCRIPCIÓN

Mascarillas desechable plana con tiras de sujeción, posee una eficiencia de filtración bacteriana de 99%. Protege la nariz y la boca para minimizar los contactos infecciosos en los medios quirúrgicos, dental, médico y en todos los demás ambientes estériles o sensibles. Esta fabricada con 3 capas de tela no tejida (capa externa 25 g / fabric tela no tejida doble S, capa interna 25 g / m? tela no tejida respetuosa con la piel), una capa de tela soplada por fusión (Eficiencia de filtración > 95%, 25 g / m?), la capacidad de filtración general supera el 95%.

Características

MATERIAL: Tela no tejida de plipropileno

Número de capas: 3

Capa interna: Tela no tejida de polipropileno, tela suave.

Capa media (filtro)

Capa externa: Tela no tejida de polipropileno, a prueba de agua.

Diseño:

Mascarilla descartable de 3 pliegues con tiras de sujeción.

Debe estar dotada de un medio por el cual se puede ceñir estrechamente sobre la nariz, boca y barbilla de quien la lleva puesta y que garantice que la mascarilla se ciñe estrechamente en los laterales.

Puente nasal: Barra moldeable de adaptación anatómica a la nariz en el borde superior de la mascarilla, la misma que debe estar protegida para no lesionar la piel ni producir incomodidad al usuario.

Requisitos de desempeño para las mascarillas quirúrgicas Tipo I

Eficacia de filtración bacteriana (BFE) (%): ≥ 95

Presión Diferencial (Pa/cm²): < 40

Carga Biológica (limpieza microbiana) (ufc/g): ≤ 30

Marcado, etiquetado y envasado

Tiene la siguiente información indicada en el envase en que se suministra la mascarilla:

a) Número de la norma técnica peruana (NTP 329.200), mediante sello o sticker.

b) Presentación en cajas de 50 unidades.



Declaration of Conformity

Manufacturer: **Anqing Mayfield Medical Limited**
Jingwu Road, Tongcheng Economic and Technological Development
Zone, Anqing City, Anhui Province, CHINA
whose single Luxus Lebenswelt GmbH
Authorized EU- Kochstr.1, 47877, Willich, Germany
Representative: DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

Product Name: **Disposable Face Masks**

Classification: **I of ANNEX IX of Directive 93/42/EEC**

Conformity Assessment Route: **Annex III**

We here declared that above mentioned product met the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General Applicable Directives:
Medical Devices DIRECTIVE

Harmonized Standards:

EN ISO 13485:2016

EN ISO 10993

EN 980-2003

EN 14683

EN ISO 14971-2007

Signature:

周苹 zhouping

Name: 周苹

Title: +86-0556-6181088

Position: General manager

Seal

2020-07-17



**Fiscal Year 2020****VERIFICATION OF FDA REGISTRATION**

This certifies that:

Anqing Mayfield Medical Limited**Jingwu Road, Tongcheng Economic and Technological Development Zone, Anqing City,
Anhui Province, 231400, CHINA**has completed the FDA Establishment Registration and Device Listing with the US Food & Drug
Administration, through UCL-REG SERVICE INC.**Owner/Operator Number: 10076152****Listing No.**

D411432

Product Code:

QKR

Device Name:Face mask (except N95 respirator) for general
public/healthcare personnel per IIE guidance-

Disposable Face Mask

D411433

MSH

Respirator, surgical-
Folding Mask

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UCL-REGSERVICE INC.

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NEW CASTLE DE 19802 USAFor and on behalf of
UCL-REG SERVICE INC.
Authorized Signature(s)

Cert. No.: M201061

Issued Date: July 07 2020

Expiration Date: 31 December 2021