

DOCUMENTACIÓN AUTOGUARDADA CONFIDENCIALMENTE POR
LA EMPRESA DISTRIBUIDORA INDUSTRIAL
FAGY SUMINISTROS Y SERVICIOS GENERALES S.A.C.
RUC: 209603281315 CEL: 996011287 / 911 / 960144
Página Web: www.fagy.com.pe - Correo: ventas@fagy.com.pe



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.	Product Code:	Device Name:
D411432	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance- Disposable Face Mask
D411433	MSH	Respirator, surgical- Folding Mask

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.



UCL-REGSERVICE INC.
602 ROCKWOOD ROAD, WILMINGTON,
NEW CASTLE DE 19802 USA

For and on behalf of
UCL-REG SERVICE INC.

(Authorized Signatory(s))

Cert. No.: M201061
Issued Date: July 07 2020
Expiration Date: 31 December 2020



Declaration of Conformity

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

Product Name: **Disposable Face Masks**

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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 zhou ping

Name: 周苹

Title: +86-0556-6181088

Position: General manager

Sea

2020-07

