# EC REP CERTIFICATE

## CMC MEDICAL DEVICES & DRUGS SL
## NO. CMC/CE/2020/14072020.13

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

**Suzhou SHIYIFANG Biotechnology Co., Ltd**
**Room 302, building 12, northwest area, Suzhou nano City, No. 99, Jinjihu Avenue, Suzhou Industrial Park, Jiangsu Province, China**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1719/2020**

CE

Issued on: 14/07/2020

Valid until: 13/07/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

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**ANNEX I Medical Device Products**

**Medical Nitrile Inspection Gloves**

CE

# EC Declaration of Conformity

*Manufacturer:*

SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD

ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO.99, JINJIHU AVENUE,SUZHOU INDUSTRIAL PARK,JIANGSU PROVINCE,CHINA

XINGYU XU
Tel: +86 15952427435
E-mail:1067704849@qq.com

*whose single Authorized EU-Representative:*

**M/s CMC Medical Devices & Drugs S.L.**
C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

We, the manufacturer, herewith declare that the products

MEDICAL NITRILE INSPECTION GLOVES
XS
S
M
L
XL

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO.99, JINJIHU AVENUE,SUZHOU INDUSTRIAL PARK,JIANGSU PROVINCE,CHINA

SUZHOU 2020.7.13
*Place, date*

XINGYU XU
*Legally binding signature, Function*