

CE Declaration of conformity CE

According to In Vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer: GUANGZHOU JET BIO-FILTRATION CO., LTD
No.1 DouTang Road, YongHe Development Zone,
511356 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Authorized Akralab, S.L.

Representative: Pol. Ind. Las Atalayas Av. de la Antigua Peseta, 77 Buzón
20212 · 03114 Alicante · Spain

Description/Category: Disposable Laboratory Plastic Products.

Plastic Pipets Products Series, Centrifuge Tubes Products Series, Cell and Tissue Culture Products, Disposable Filtration Products, ELISA Microplate, Inoculating Loops and Needles, Liquid Transfer Troughs, Cuvette, Pipette Micro Tips, Deep-Well Plates, Serum & Sample Tubes, Freezing Tubes and PCR Tubes for In Vitro Diagnostics.

Device Classification : Others, Self-Declaration

Conformity assessment Route: Annex III

THE UNDERSIGNED HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. WE, THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC.

Quality Manager

Guangzhou

February 21, 2019

(Place and date of issue)

York Zhang

(Name and signature of authorized person)





America

CERTIFICATE

No. QS2 087492 0006 Rev. 00

Certificate Holder:

GUANGZHOU JET BIO-FILTRATION CO., LTD.
No.1 DouTang Road
YongHe Development Zone
511356 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of the Plastic Pipets Products Series, Centrifuge Tubes Products Series, Cell and Tissue Culture Products, Disposable Filtration Products, ELISA Microplate, Inoculating Loops and Needles, Liquid Transfer Troughs, Cuvette, Pipette Micro Tips, Deep-Well Plates, Serum & Sample Tubes, Freezing Tubes and PCR Tubes for In-Vitro Diagnostics

Standard(s):

ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

M6417

Effective Date:

2018-09-12

Expiry Date:

2020-06-16

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Date of Issue: 2018-09-13

(Arie Henkin)



America

CERTIFICATE

No. QS5 087492 0005 Rev. 00

Certificate Holder:

GUANGZHOU JET BIO-FILTRATION CO., LTD.
No.1 DouTang Road
YongHe Development Zone
511356 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production
and Distribution of Disposable Laboratory
Plastic Products and Rechargeable Pipet Aids

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

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(Arie Henkin)

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