

# NANTONG MICHAEL IRRADIATION CO., LTD

## CERTIFICATE OF GAMMA STERILIZATION

Date:2021-08-25

STERILE COMPANY	NANTONG MICHAEL IRRADIATION CO.,LTD
EXPORTER	ZHEJIANG FIRSD GROUP CO., LTD.
IMPORTER	Global Trade Technology – Comércio, Importação e Exportação Ltda - EPP. Av. José Antonio Miziara n 221 - Distrito Ind. José Aparecido Tomé - Jaboticabal – SP. – 14.874-002 Fone/Fax: (16) 4042-4000 CPNJ: 07.610.601/0001-65 INSCRIÇÃO ESTADUAL: 391.173.147.116 E-mail: <a href="mailto:importacao@globaltradebr.com.br">importacao@globaltradebr.com.br</a>
灭菌日期 DATE OF STERILIZATION	25 <sup>h</sup> AUG 2021
Invoice Number: 2021F02J39 Product: AS ATTACHMENT	
要求 GAMMA 剂量 MIN GAMMA DOSE 25KGY MAXIUM GAMMA DOSE:40KGY	
南通市迈克尔辐照有限公司 特此证明上述产品已经本公司 GAMMA 射线消毒 NANTONG MICHAEL IRRADIATION CO., LTD hereby warranty that all products mentioned above have been sterilized by GAMMA RAY	

STAMP:

SIGNATURE

郑建达



**ATTACHMENT**

ITEM NO.	DESCRIPTION	QTY	LOT NO	MFG date	EXP date
GT-GP10L	pipette tip 10ul long	1,000	GTGP10L202108	08/2021	08/2026
GT-GP200	pipette tip 200ul	1,000	GTGP200202108	08/2021	08/2026
GT-GP200L	pipette tip 200ul long	300	GTGP200L202108	08/2021	08/2026
GT-GP1000	pipette tip 1000ul	1,000	GTGP10002021008	08/2021	08/2026
GT-GP1000L	pipette tip 1000ul long	300	GTGP1000L202108	08/2021	08/2026
GT-GP10LF	pipette tip 10ul long with filter	300	GTGP10LF202108	08/2021	08/2026
GT-GP200F	pipette tip 200ul with filter	300	GTGP200F202108	08/2021	08/2026
GT-GP200LF	pipette tip 200ul long with filter	300	GTGP200LF202108	08/2021	08/2026
GT-GP1000F	pipette tip 1000ul with filter	300	GTGP1000F202108	08/2021	08/2026
GT-GP1000LF	pipette tip 1000ul long with filter	300	GTGP1000LF202108	08/2021	08/2026
GT-GP10LFR	pipette tip 10ul long with filter in rack	5,000	GTGP10LFR202108	08/2021	08/2026
GT-GP200LFR	pipette tip 200ul long with filter in rack	5,000	GTGP200FR202108	08/2021	08/2026
GT-GP1000LFR	pipette tip 1000ul long with filter in rack	1,000	GTGP1000LFR202108	08/2021	08/2026
GT-GP20LFR	pipette tip 20ul long with filter in rack	1,000	GTGP20FR202108	08/2021	08/2026
GT-GP100LFR	pipette tip 100ul long with filter in rack	5,000	GTGP100LFR202108	08/2021	08/2026
GT-GP10LR	pipette tip 10ul long in rack	5,000	GTGP10R202108	08/2021	08/2026
GT-GP20LR	pipette tip 20ul long in rack	1,000	GTGP20R202108	08/2021	08/2026
GT-GP100LR	pipette tip 100ul long in rack	5,000	GTGP100R202108	08/2021	08/2026
GT-GP200LR	pipette tip 200ul long in rack	5,000	GTGP200LR202108	08/2021	08/2026
GT-GP1000LR	pipette tip 1000ul long in rack	1,000	GTGP1000LR202108	08/2021	08/2026



浙江福士达集团有限公司  
ZHEJIANG FIRSD GROUP CO.,LTD

## TEST REPORT for DNase&RNase activity

Manufacturer: **ZHEJIANG FIRSD GROUP CO.,LTD**

INVOICE Number: 2021F02J39

Date of Issuing: 2021/08/2

Importer: Global Trade Technology – Comércio, Importação e Exportação Ltda - EPP.

Av. José Antonio Miziara n 221 - Distrito Ind. José Aparecido Tomé -

Jaboticabal – SP. – 14.874-002 Fone/Fax: (16) 4042-4000

CPNJ: 07.610.601/0001-65 INSCRIÇÃO ESTADUAL: 391.173.147.116

E-mail: [importacao@globaltradebr.com.br](mailto:importacao@globaltradebr.com.br)

PRDUCTS : AS ATTACHMENT

Sample on :2021-08-20      Start of test:2021-08-20      End of test:2021-08-25

Sample type NO:5050- Analysis of RNase& DNase activity

<u>Parameter</u>	<u>Result</u>
DNase&RNase activity	not detected

The test was conducted in compliance with GMP guidelines, There were no test-related deviations

浙江福士达集团有限公司  
ZHEJIANG FIRSD GROUP CO.,LTD

Attachment

ITEM NO.	DESCRIPTION	QTY	LOT NO	MFG date	EXP date
GT-GP10L	pipette tip 10ul long	1,000	GTGP10L202108	08/2021	08/2026
GT-GP200	pipette tip 200ul	1,000	GTGP200202108	08/2021	08/2026
GT-GP200L	pipette tip 200ul long	300	GTGP200L202108	08/2021	08/2026
GT-GP1000	pipette tip 1000ul	1,000	GTGP10002021008	08/2021	08/2026
GT-GP1000L	pipette tip 1000ul long	300	GTGP1000L202108	08/2021	08/2026
GT-GP10LF	pipette tip 10ul long with filter	300	GTGP10LF202108	08/2021	08/2026
GT-GP200F	pipette tip 200ul with filter	300	GTGP200F202108	08/2021	08/2026
GT-GP200LF	pipette tip 200ul long with filter	300	GTGP200LF202108	08/2021	08/2026
GT-GP1000F	pipette tip 1000ul with filter	300	GTGP1000F202108	08/2021	08/2026
GT-GP1000LF	pipette tip 1000ul long with filter	300	GTGP1000LF202108	08/2021	08/2026
GT-GP10LFR	pipette tip 10ul long with filter in rack	5,000	GTGP10LFR202108	08/2021	08/2026
GT-GP200LFR	pipette tip 200ul long with filter in rack	5,000	GTGP200FR202108	08/2021	08/2026
GT-GP1000LFR	pipette tip 1000ul long with filter in rack	1,000	GTGP1000LFR202108	08/2021	08/2026
GT-GP20LFR	pipette tip 20ul long with filter in rack	1,000	GTGP20FR202108	08/2021	08/2026
GT-GP100LFR	pipette tip 100ul long with filter in rack	5,000	GTGP100LFR202108	08/2021	08/2026
GT-GP10LR	pipette tip 10ul long in rack	5,000	GTGP10R202108	08/2021	08/2026
GT-GP20LR	pipette tip 20ul long in rack	1,000	GTGP20R202108	08/2021	08/2026
GT-GP100LR	pipette tip 100ul long in rack	5,000	GTGP100R202108	08/2021	08/2026
GT-GP200LR	pipette tip 200ul long in rack	5,000	GTGP200LR202108	08/2021	08/2026
GT-GP1000LR	pipette tip 1000ul long in rack	1,000	GTGP1000LR202108	08/2021	08/2026



浙江福士达集团有限公司  
ZHEJIANG FIRSD GROUP CO.,LTD

ZHEJIANG FIRSD GROUP CO.,LTD

218 tiyuchang road, xiacheng area, Hangzhou, China

**CERTIFICATE OF ANALYSIS**

产品合格证明

**Manufacturer:** ZHEJIANG FIRSD GROUP CO.,LTD

INVOICE Number: 2021F02J39

定单号

Date of Issuing: 2021/08/25

Importer: Global Trade Technology – Comércio, Importação e Exportação Ltda - EPP.

Av. José Antonio Miziara n 221 - Distrito Ind. José Aparecido Tomé -

Jaboticabal – SP. – 14.874-002 Fone/Fax: (16) 4042-4000

CPNJ: 07.610.601/0001-65 INSCRIÇÃO ESTADUAL: 391.173.147.116

E-mail: [importacao@globaltradebr.com.br](mailto:importacao@globaltradebr.com.br)

出证日期

PRODUCT NAME	AS ATTACHMENT																										
Sample Quantity 检测数量	3000pcs	QUANTITY																									
<p><b>Results of Testing</b> 检测结果</p> <table> <tr> <td>Physical Testing:</td> <td>PASS ✓</td> <td>FAILED □</td> <td>N/A □</td> </tr> <tr> <td>物理性能</td> <td>合格</td> <td>不合格</td> <td>不检测</td> </tr> <tr> <td>Chemical Testing:</td> <td>PASS ✓</td> <td>FAILED □</td> <td>N/A □</td> </tr> <tr> <td>化学性能</td> <td>合格</td> <td>不合格</td> <td>不检测</td> </tr> <tr> <td>Biological Testing:</td> <td>PASS ✓</td> <td>FAILED □</td> <td>N/A □</td> </tr> <tr> <td>生物性能</td> <td>合格</td> <td>不合格</td> <td>不检测</td> </tr> </table> <p>Remark: for biological testing, pls mark which item included: Sterility ✓ Pyrogen □</p> <p>备注: 请注明生物性能检测项目, 无菌检测, 热原检测</p>				Physical Testing:	PASS ✓	FAILED □	N/A □	物理性能	合格	不合格	不检测	Chemical Testing:	PASS ✓	FAILED □	N/A □	化学性能	合格	不合格	不检测	Biological Testing:	PASS ✓	FAILED □	N/A □	生物性能	合格	不合格	不检测
Physical Testing:	PASS ✓	FAILED □	N/A □																								
物理性能	合格	不合格	不检测																								
Chemical Testing:	PASS ✓	FAILED □	N/A □																								
化学性能	合格	不合格	不检测																								
Biological Testing:	PASS ✓	FAILED □	N/A □																								
生物性能	合格	不合格	不检测																								
<p>CONCLUSION: 结论</p> <p>is to certify that all the items manufactured as per Invoice No: <u>2021F02J39</u> have passed all of the tests and meet all of the requirements.</p> <p>格证明证实按定单号 <u>2021F02J39</u> 生产的本批产品经各项检测均合格, 符合所有标准。</p>																											
<p>浙江福士达集团有限公司 ZHEJIANG FIRSD GROUP CO.,LTD</p>		<p>Stamp 盖章</p>																									

Date: 2021/08/25

ITEM NO.	DESCRIPTION	QTY	LOT NO	MFG date	EXP date
CE1161	Model CE1161 - Spinplus Centrifuge for 8*15ml conical tubes, max. Speed 5000rpm - TC-Spinplus-8 (8011604model) for veterinary purposes. Power 110V. Trade Mark: Centrilab. Manufacturing Year: 2021	100	CE116120210521	21/05/2021	
CE1161U	Model CE1161 - Spinplus Centrifuge for 8*15ml conical tubes, max. Speed 5000rpm - TC-Spinplus-8 (8011604model) for veterinary purposes. Power 220V. Trade Mark: Centrilab. Manufacturing Year: 2021	100	CE1161U20210521	21/05/2021	
8011154V	METEOR HANDHELD CENTRIFUGE METEOR 7.2K, 110-220V	24	8011154V20210521	21/05/2021	
8011154V	METEOR HANDHELD CENTRIFUGE METEOR 7.2K, 110-220V	6	8011154V20210521	21/05/2021	
GT-GP10L	pipette tip 10ul long	1,000	GTGP10L202108	08/2021	08/2026
GT-GP200	pipette tip 200ul	1,000	GTGP200202108	08/2021	08/2026
GT-GP200L	pipette tip 200ul long	300	GTGP200L202108	08/2021	08/2026
GT-GP1000	pipette tip 1000ul	1,000	GTGP10002021008	08/2021	08/2026
GT-GP1000L	pipette tip 1000ul long	300	GTGP1000L202108	08/2021	08/2026
GT-GP10LF	pipette tip 10ul long with filter	300	GTGP10LF202108	08/2021	08/2026
GT-GP200F	pipette tip 200ul with filter	300	GTGP200F202108	08/2021	08/2026
GT-GP200LF	pipette tip 200ul long with filter	300	GTGP200LF202108	08/2021	08/2026
GT-GP1000F	pipette tip 1000ul with filter	300	GTGP1000F202108	08/2021	08/2026
GT-GP1000LF	pipette tip 1000ul long with filter	300	GTGP1000LF202108	08/2021	08/2026
GT-GP10LFR	pipette tip 10ul long with filter in rack	5,000	GTGP10LFR202108	08/2021	08/2026
GT-GP200LFR	pipette tip 200ul long with filter in rack	5,000	GTGP200LFR202108	08/2021	08/2026
GT-GP1000LFR	pipette tip 1000ul long with filter in rack	1,000	GTGP1000LFR202108	08/2021	08/2026

GT-GP20LFR	pipette tip 20ul long with filter in rack	1,000	GTGP20FR202108	08/2021	08/2026
GT-GP100LFR	pipette tip 100ul long with filter in rack	5,000	GTGP100LFR202108	08/2021	08/2026
GT-GP10LR	pipette tip 10ul long in rack	5,000	GTGP10R202108	08/2021	08/2026
GT-GP20LR	pipette tip 20ul long in rack	1,000	GTGP20R202108	08/2021	08/2026
GT-GP100LR	pipette tip 100ul long in rack	5,000	GTGP100R202108	08/2021	08/2026
GT-GP200LR	pipette tip 200ul long in rack	5,000	GTGP200LR202108	08/2021	08/2026
GT-GP1000LR	pipette tip 1000ul long in rack	1,000	GTGP1000LR202108	08/2021	08/2026
GTVIB-600	VARIABLE VOLUME MICROPIPETTES 10-100uL (BASIC RANGE)	500	GTVIB600202108	08/2021	



## **Certificate of Purity -PCR clean**

**Sample on :2021-08-20    Start of test:2021-08-20    End of test:2021-08-25**

**This package contains a high quality consumable manufactured under the PCR clean Purity Standard.**

**The PCR clean consumables are produced in a Class 100000 clean room environment.**

**For this product we certificate the following**

**Free of detectable**

**Human DNA**

**DNase**

**RNase**

**PCR inhibitors**

**The certification comprises the following tests:**

### **Human DNA Contamination Test**

**A PCR master mix is prepared for the detection of human DNA.**

**15 samples are rinsed one after another with DNA-free water .10ul of this solution is added to 15ul master mix, PCR is done for 30 cycles**

**The emittance of sybr gerrn-dnduced fluorescence is detected in samples and controls ,for the samples to pass certification, no fluorescence must be found corresponding to the negative control.**

### **DNase Test**

**15 samples are rinsed one after another with DNA-free water.17ul of these solutions are mixed with 3ul Dnase-buffer containing 100bp DNA-ladder in a DNase-free tube. A positive control is spiked with DNase,a negative control contains DNA-free water. All tubes are incubated for 24houe at 37°C**



The DNA is analyzed by agarose-gel electrophoresis. DNase contamination is indicated by degradation of the DNA ladder. For samples to pass certification, the relative intensities of the DNA pattern of the samples must correspond to the negative control.

#### RNase Test

15 samples are rinsed one after another with DNA-free water. 17ul of these solutions are mixed with 3ul Dnase-buffer containing 100bp DNA-ladder in a DNase-free tube. A positive control is spiked with DNase, a negative control contains DNA-free water. All tubes are incubated for 24 hours at 37°C

The RNA is analyzed by agarose-gel electrophoresis. RNase contamination is indicated by degradation of the RNA ladder. For samples to pass certification, the relative intensities of the RNA pattern of the samples must correspond to the negative control

#### PCR Inhibitor Test

15 samples are rinsed one after another with DNA-free water. 10ul of these solutions is added to 15ul master mix plus 16pg human DNA. PCR is done for 30 cycles.

The emittance of Sybr Green-induced fluorescence is detected in samples and controls. For the samples to pass certification, the CT-values of the samples are compared with the positive control (containing 16pg human DNA). The difference of the CT-value between the samples and the control must be in range of  $\pm 2$  cycles

Aug, 2021

QC: 郑涛

Parameter

Result

DNase & RNase activity, PCR Inhibitor

not detected

The test was conducted in compliance with GMP guidelines, There were no test-related deviations

浙江福士达集团有限公司  
ZHEJIANG FIRSD GROUP CO., LTD

施俊

施俊

Attachment

ITEM NO.	DESCRIPTION	QTY/UNIT	LOT NO	MFG date	EXP date
GT-GP10L	pipette tip 10ul long	1,000	GTGP10L202108	08/2021	08/2026
GT-GP200	pipette tip 200ul	1,000	GTGP200202108	08/2021	08/2026
GT-GP200L	pipette tip 200ul long	300	GTGP200L202108	08/2021	08/2026
GT-GP1000	pipette tip 1000ul	1,000	GTGP10002021008	08/2021	08/2026
GT-GP1000L	pipette tip 1000ul long	300	GTGP1000L202108	08/2021	08/2026
GT-GP10LF	pipette tip 10ul long with filter	300	GTGP10LF202108	08/2021	08/2026
GT-GP200F	pipette tip 200ul with filter	300	GTGP200F202108	08/2021	08/2026
GT-GP200LF	pipette tip 200ul long with filter	300	GTGP200LF202108	08/2021	08/2026
GT-GP1000F	pipette tip 1000ul with filter	300	GTGP1000F202108	08/2021	08/2026
GT-GP1000LF	pipette tip 1000ul long with filter	300	GTGP1000LF202108	08/2021	08/2026
GT-GP10LFR	pipette tip 10ul long with filter in rack	5,000	GTGP10LFR202108	08/2021	08/2026
GT-GP200LFR	pipette tip 200ul long with filter in rack	5,000	GTGP200LFR202108	08/2021	08/2026
GT-GP1000LFR	pipette tip 1000ul long with filter in rack	1,000	GTGP1000LFR202108	08/2021	08/2026
GT-GP20LFR	pipette tip 20ul long with filter in rack	1,000	GTGP20LFR202108	08/2021	08/2026
GT-GP100LFR	pipette tip 100ul long with filter in rack	5,000	GTGP100LFR202108	08/2021	08/2026
GT-GP10LR	pipette tip 10ul long in rack	5,000	GTGP10LR202108	08/2021	08/2026
GT-GP20LR	pipette tip 20ul long in rack	1,000	GTGP20LR202108	08/2021	08/2026
GT-GP100LR	pipette tip 100ul long in rack	5,000	GTGP100LR202108	08/2021	08/2026
GT-GP200LR	pipette tip 200ul long in rack	5,000	GTGP200LR202108	08/2021	08/2026
GT-GP1000LR	pipette tip 1000ul long in rack	1,000	GTGP1000LR202108	08/2021	08/2026
GT-GP1000LR	pipette tip 1000ul long in rack	1,000	GTGP1000LR202108	08/2021	08/2026
WE14	Cryotube Vol. 1.8mL, PP material, graduated up to 2mL, leak-proof, silicon rubber liner mounted in cap	1620	WE1420210512	05/2021	05/2026
GT-GP15	Centrifuge tube		GTGP15202108	08/2021	08/2026
GT-GP50	centrifuge tube 50ml		GTGP50202108	08/2021	08/2026