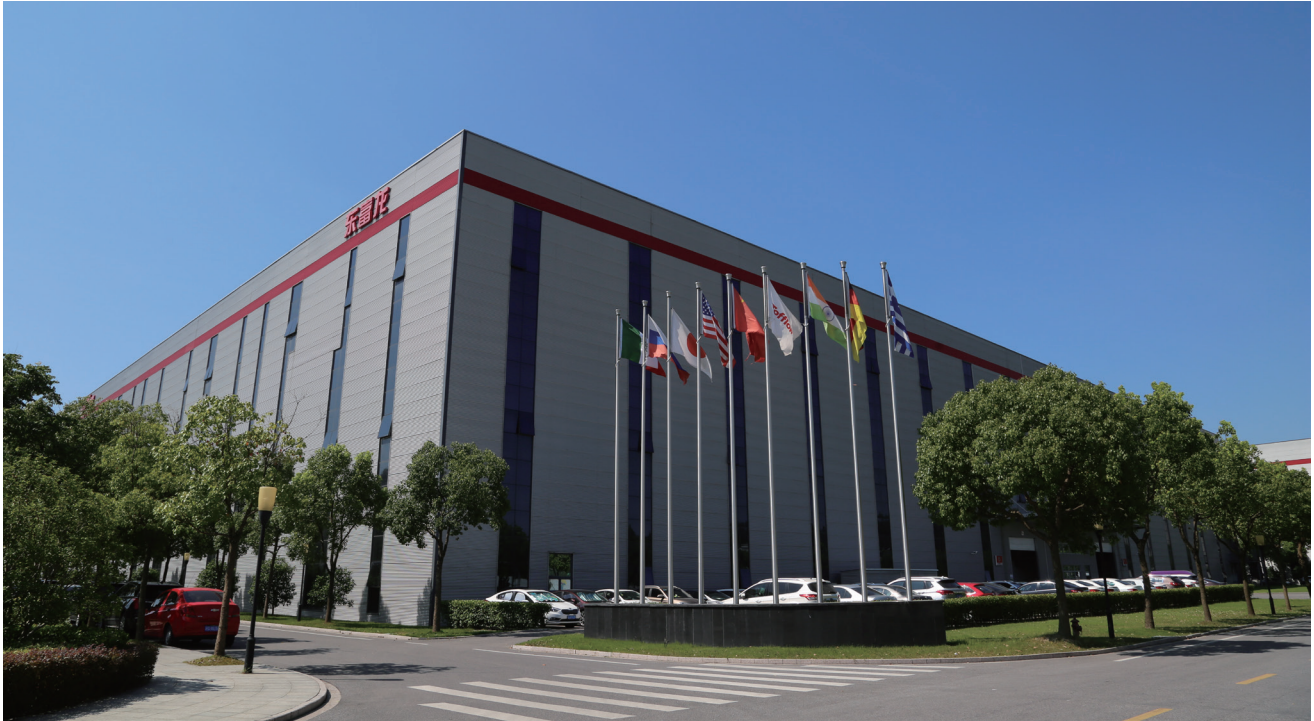


**Tofflon**



**SUF Single-use Fermentation  
Reactor System**

# Tofflon Life Science Co.,Ltd.



**F**ounded in 1993, Tofflon Science and Technology Group Co., Ltd. (SZ:300171) is a pioneering Chinese enterprise in the field of biotechnology, with a rich history of 30 years. With annual sales reaching 5.4 billion RMB in 2022 and a global workforce of 5,500 employees, Tofflon has established over 50 offices worldwide, embodying a globalized business and team.

Tofflon Life Sciences Co., Ltd., the flagship subsidiary within the group, plays a pivotal role in their portfolio. It focuses on the research and development of cutting-edge technologies in the biopharmaceutical and life science industries. As a strategic division Tofflon life science provides one-stop solutions and services that integrate bioprocessing equipment, core consumables like sterile bags, culture media, resins to further enquire and professionally.

- In the realm of cell therapy, we offer complete solutions for the preparation and production of immune cell pipelines, stem cell pipelines, tumor cell vaccines, and more.
- For gene therapy, we provide overall solutions for the research, development, and industrialization of nucleic acid drugs (mRNA/DNA) and viral vector drugs.
- In the field of biological sample banking, we conduct research and development of automatic sample storage management systems to provide comprehensive solutions for cell seed and tissue samples.
- In the consumables sector, we have developed a complete range of products including disposable bags (culture bags, mixing bags, storage bags), bio-reagents (culture media, cryoprotectants, Ficoll, growth factors), resin (GFC, AC, AEX, CEX, HIC, MMC), filtration (microfiltration, deep filtration, TFF, cassette), and hard packaging materials.
- We also focus on disinfection, offering comprehensive solutions for clean room disinfection, surface and external disinfection, infection control, terminal disinfection, and multi-drug resistant microorganism disinfection, ensuring effective environmental disinfection.

Leveraging Tofflon Group's extensive expertise in design, manufacturing, engineering construction, and after-sales service worldwide, Tofflon Life Sciences Division is committed to serving the biopharmaceutical industry with enhanced speed and professionalism.

# Single-use Fermentation Reactor System

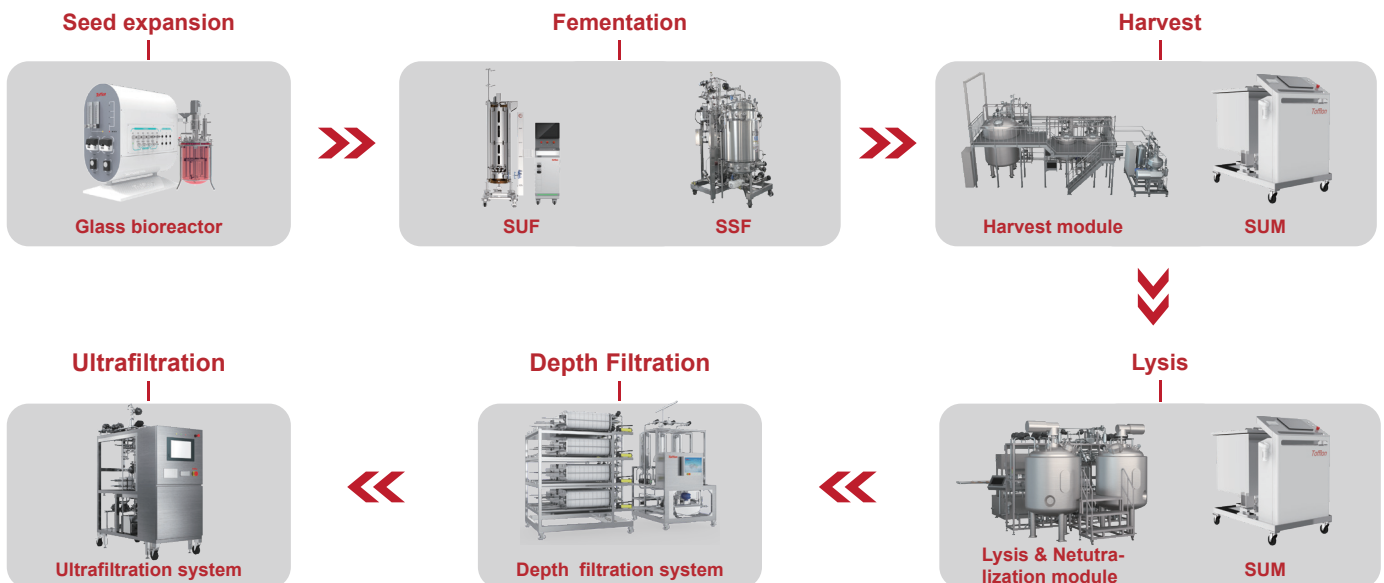
**SUF** single-use fermentation reactor system: Products designed specifically for microbial fermentation meet the needs of high density microbial fermentation; The equipment has strong mixing capacity, excellent oxygen mass transfer capacity, efficient temperature control capacity, automatic defoaming capacity and powerful exhaust treatment capacity, which can meet the needs of rapid and high-density growth of microorganisms, high oxygen demand and rapid heat dissipation. The application of single-use technology reduces batch turnover and time-consuming CIP and SIP cycles, reduces cost and improves productivity while adopting geometric design consistent with standard stainless steel fermentation systems, which can be used for the culture of microorganisms such as Escherichia coli, Pseudomonas and yeast, facilitating plasmid process development and large-scale production.

## Technical characteristics

- ✔ Highly standardized hardware and software products, pre-configured with algorithms for controlling biological process parameters such as pH, dissolved oxygen, temperature, agitation, pressure, foam, liquid level, gas/liquid flow.
- ✔ Support redundant sensor loops, such as pH, temperature, or dissolved oxygen.
- ✔ There is no need for customized development, hardware and software design, etc.
- ✔ Reduce service time of loop test, FAT, SAT, etc.
- ✔ Shorten the project cycle by about 30% compared with customized system projects.
- ✔ Powerful custom configuration function, can be convenient for a variety of strategy control association, dissolved oxygen can be associated with a maximum of 4 strategies, pH can be associated with a maximum of 2 strategies, but also can be associated with pressure, tail gas temperature, tank weight, foam, etc.

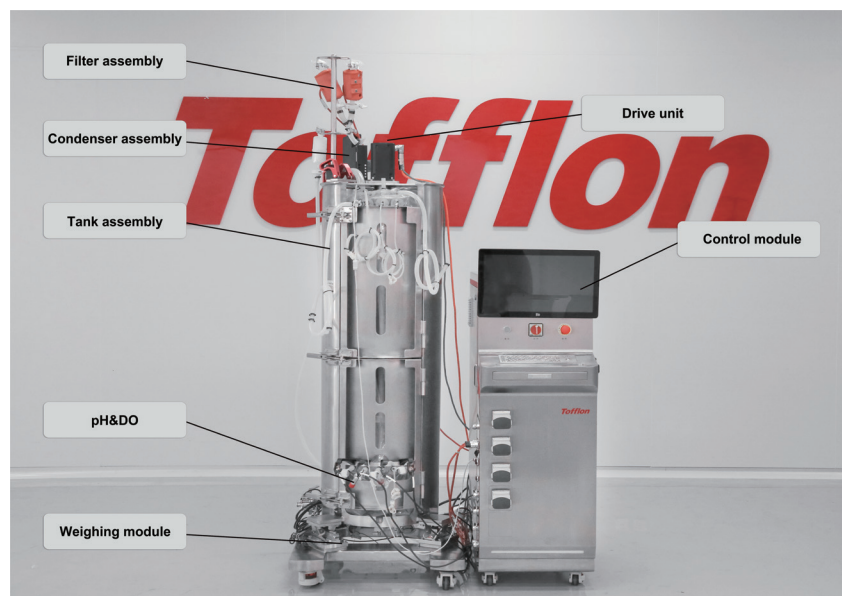


## Process flow chart



## Equipment introduction

- ✔ Tank part: working volume diameter to height ratio, mixing and inner diameter ratio, are consistent with the stainless steel system, so as to ensure the consistency of the process with the stainless steel system.
- ✔ Mixing impeller part: equipped with multi-layer 6 straight blade mixing impeller, have better mixing effect. Can be equipped with defoaming blade, avoid foam to the tail end and solution pollution.
- ✔ Stirring shaft part: adopt the design form of magnetic stirring shaft at the top to ensure sterility and stability. At the same time, the bottom support can ensure the stability of the stirring shaft in the process of rotation, but also can meet the low level culture.
- ✔ Baffle part: using 4 baffles, with high system power and strong mixing capacity.
- ✔ Ventilation disc part: the ventilation disc adopts ring design, which can meet the requirements of high flux bubbling, and will not have any influence on the ventilation disc due to the ventilation pressure and velocity.
- ✔ Condensation system: SUF microbial reaction bag is equipped with condensation bag, the equipment is equipped with semiconductor condensation system, to ensure that the tail end will not be blocked and avoid the risk of bacteria.
- ✔ Distributor section: Provides ventilation and venting up to 2VVM, single ventilation KLa up to 600 h<sup>-1</sup>.



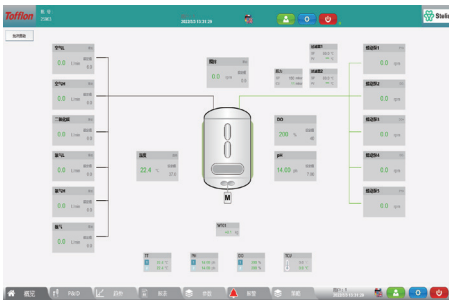
## Features of SUF software

- ✔ Provide fully automatic operation and complete data record, in accordance with the requirements of 21CFR Part11 regulations.
- ✔ Remote alarm (email, SMS or voice notification) can be provided according to demand.
- ✔ It can open relevant communication protocols to connect with SCADA systems of various companies.
- ✔ Comply with pharmaceutical GMP standards to perform three-level authority management.

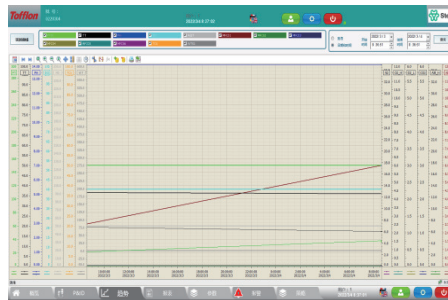
## Control specification

- ✓ Mixing control: imported Kohl Morgan servo motor is adopted, which can be accurate to  $\pm 1$ rpm, to ensure that the long time operation is barrier-free, and the motor noise is less than 70dB.
- ✓ Temperature control: jacket +TCU unit PID temperature control, remote start and stop TCU, more convenient operation.
- ✓ Weighing control: four-foot Load Cell Mettler weighing sensor, integrated weighing module, C3 precision, control accuracy up to 0.3%.
- ✓ pH control: The pH electrode uses the reusable smart electrode or the traditional electrode, the control range is 1~14, the accuracy is 0.02, PH control can be associated with CO<sub>2</sub> gas and alkali pump PID control.
- ✓ DO control: DO electrode uses reusable intelligent electrode or traditional optical electrode, range of 0-200% accuracy  $\pm 3\%$ , DO control is usually associated with AIR, N<sub>2</sub>, O<sub>2</sub> gas PID control.
- ✓ Feeding control: multiple feeding modes such as continuous feeding and interval feeding are optional. The feeding rate and time can be set according to the process requirements.
- ✓ Exhaust gas heating control: exhaust gas heating control between 0-65 degrees, to ensure that there is no condensate in the filter, exhaust gas emission.
- ✓ Pressure control: The system comes with pressure detection function and pressure monitoring function. Pressure detection can be used for integrity detection of bags before use to avoid defects in bags. Pressure monitoring function, in order to ensure the safety of bag pressure during the culture process.
- ✓ Level defoaming control: Integrated level defoaming sensor to ensure that foam will not clog the ventilation pipeline and cause pollution.

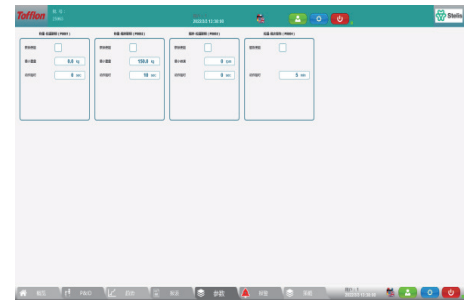
## SUF software control system



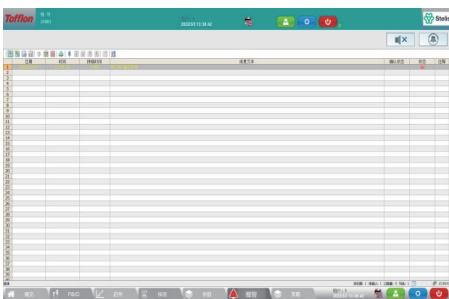
Overview interface



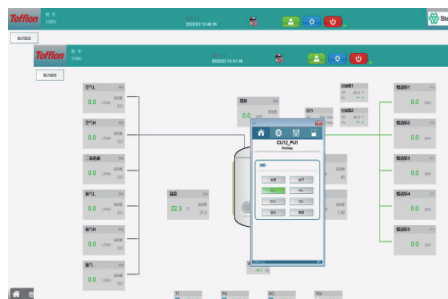
Trend interface



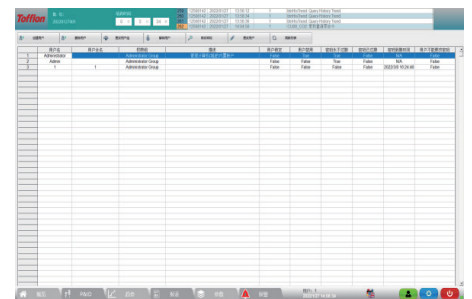
Parameter interface



Alarm interface



Policy interface



User interface



## ■ Consumable introduction

Designed for the upstream culture of microorganisms such as Escherichia coli, Pseudomonas and yeast, disposable fermentation bags can maintain integrity under high speed, turbulent mixing and high flow conditions. Meanwhile, the design of six-straight blade disc turbine, high VVM (ventilation ratio) airflow and baffle design make it have very high OD600 value in the fermentation production of multiple microorganisms.

## ■ Consumable characteristics

- ✔ Portable to use: Single-use technology eliminates the need for cleaning and thus avoids the risk of cross-contamination.
- ✔ Stability: Made of multilayer transparent films, it provides high mechanical strength against tearing, but also provides biological inertia against fluid contact.
- ✔ Customizable: disposable fermentation bags can be customized according to customer requirements of connectors, pipes and special accessories.
- ✔ Stirring device, ventilation chassis device: to achieve rapid mixing and oxygen dissolution effect.
- ✔ A variety of connectors, sensors, or filters are available for different functions to support various upstream and downstream requirements of buffers, media, products and intermediates, and other process fluids.



## ■ Consumable configuration table

| Equipment model                             | SUF50L   | SUF200L  | SUF500L  | SUF1000L |
|---|----------|----------|----------|----------|
| Maximum working volume                      | 50L      | 200L     | 500L     | 1000L    |
| Minimum working volume                      | 10L      | 40L      | 100L     | 200L     |
| Working volume ratio (height/diameter)      | 3:1      |          |          |          |
| Diameter to height ratio of stirring paddle | 0.35     |          |          |          |
| Vent disc aperture                          | 0.5mm    |          |          |          |
| Number of apertures                         | 70       | 40       | 10       | 70       |
| Stirring rate                               | 0-300rpm | 0-250rpm | 0-200rpm | 0-150rpm |

## ■ Control Components - Configuration table

|                                     |   | SUF50L          | SUF200L | SUF500L | SUF1000L |
|-------------------------------------|---|-----------------|---------|---------|----------|
| <b>Controller basic information</b> | Material                                | S304            |         |         |          |
|                                     | Length * width * height (mm)            | 500*900*1700    |         |         |          |
|                                     | Weight                                  | 210Kg           |         |         |          |
|                                     | Package size(mm)                        | 800*1200*2000   |         |         |          |
| <b>Equipment configuration</b>      | MFC Air                                 | 1               |         |         |          |
|                                     | MFC O2                                  | 1               |         |         |          |
|                                     | MFC O02                                 | Optional Scheme |         |         |          |
|                                     | MFC N2                                  | Optional Scheme |         |         |          |
|                                     | Tail heating jacket                     | 2               |         |         |          |
|                                     | 313 Peristaltic Pump (constant speed)   | 2               |         |         |          |
|                                     | 313 Peristaltic pump (speed regulation) | 2               |         |         |          |
|                                     | Temperature probe PT100                 | 1               |         |         |          |
|                                     | pH                                      | 1               | 2       |         |          |
|                                     | DO                                      | 1               | 2       |         |          |
|                                     | Pressure sensor                         | 1               |         |         |          |
|                                     | Defoaming electrode                     | 1               |         |         |          |
|                                     | Weighing sensor                         | 4               |         |         |          |



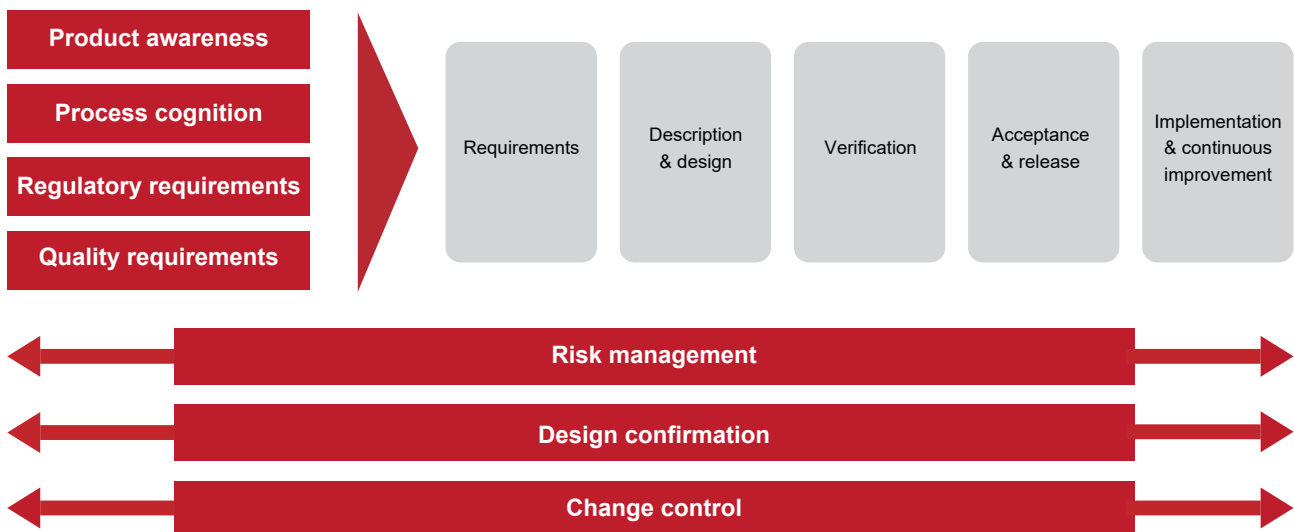
## Project Management

Three main factors determine the success of the project. Our organizational mode has been making constant update and improvement to enable you to fully achieve these goals. Through cooperation with us, you can minimize the direct resources required to manage the selection, purchase, installation, startup and verification of new production equipment.



- ✔ Reliable quality
- ✔ Short cycle
- ✔ Focus on cost

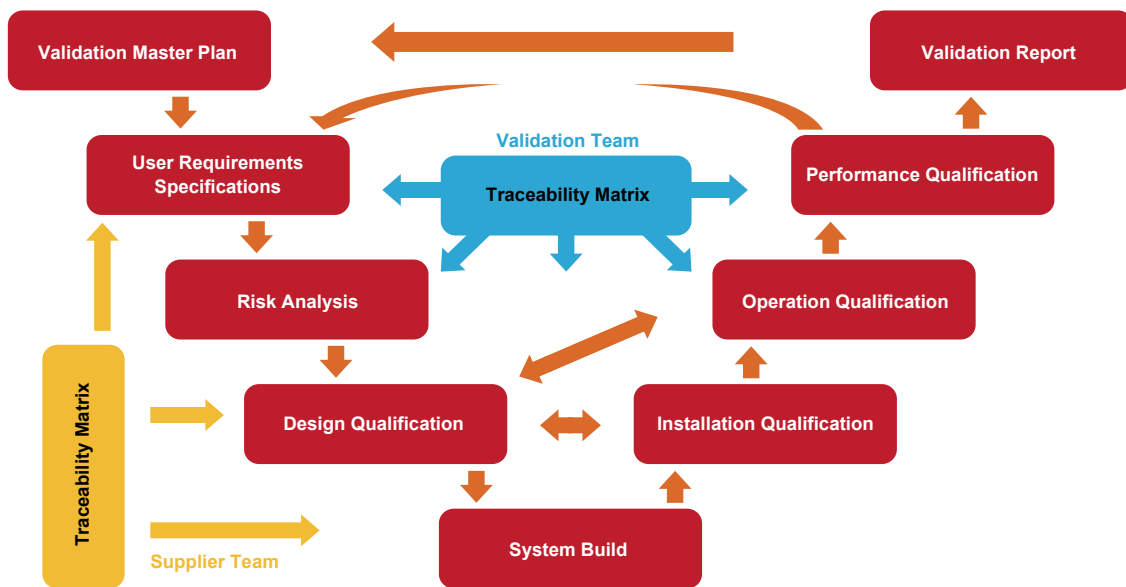
## Good Engineering Practice - GEP





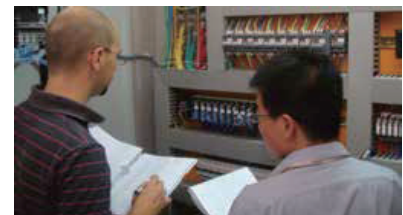


## Validation Support



## Verification Document System

- ✔ Complete document system
- ✔ Strict quality guarantee process
- ✔ Comply with cGMP confirmation scheme
- ✔ Ensure the stability and reliability of product quality





**Tofflon** Tofflon Science and Technology Group Co.,Ltd.

Address: No.1509,Duhui Road,Shanghai,China 201108

Tel: +86 21 6490 1123 / 6490 6201

Fax: +86 21 6490 5148 / 6490 6202

E-mail: [lifescience.info@tofflon.com](mailto:lifescience.info@tofflon.com)

[www.tofflon.com](http://www.tofflon.com)