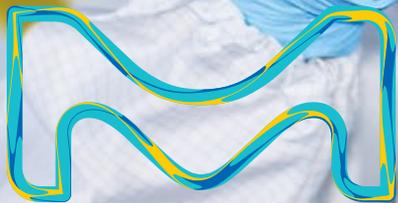


Microbial Environmental Monitoring Solutions

for the Pharmaceutical
Industry



MilliporeSigma is the U.S.
and Canada Life Science
business of Merck KGaA,
Darmstadt, Germany.

Millipore®

Preparation, Separation,
Filtration & Monitoring Products



content

GMP compliant solutions for process monitoring in pharmaceutical manufacturing

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ON GUARD

GMP compliant solutions for process monitoring in pharmaceutical manufacturing

Safety matters. The manufacture of pharmaceutical products is performed under controlled conditions. Microbial monitoring is an important part of proving the manufacturing process is under control, especially in aseptic production. The risk-based implementation of sampling plans as well as subsequent trend analysis of monitoring results, this helps to detect deviations from qualified status, prepare root cause analysis and follow up with appropriate CAPAs.

We offer a broad portfolio for microbial monitoring of aseptic pharmaceutical manufacturing including convenient and ready to use 55 mm and 90 mm agar plates,

Swabs as well as viable air samplers for ambient air and compressed gas testing. Furthermore, we provide specific concepts for monitoring of isolators and RABS to ease your workflows.

In addition to solutions for classical environmental monitoring we have irradiated granulated as well as ready prepared culture media for aseptic process simulations.

All our portfolios are supported by a broad range of services, embodying our ambition to remain one step ahead of customer demands and expectations.

Learn more on
[SigmaAldrich.com/
environmentalmonitoring](https://www.sigmaaldrich.com/environmentalmonitoring)



Accuracy

Consistent performance at every step

Our products are manufactured for high quality assured raw materials, each raw material is from a proven and audited supplier. The use of standardized manufacturing practices ensures high quality products. These conditions ensure a high quality and reliable product that makes your result trending data accurate, reliable and consistent.



Risk Reduction

We minimize risk to make your work more secure

Our product range is designed to minimize the risk of cross-contamination as well as disruption of unidirectional air flow during active air monitoring up to the highest level of cleanroom grades and isolators.

setting standards

Optimize your processes to save time and improve capacity

Our expertise and constant quality improvement programs coupled with a high level of validation and scientific data advances the environmental monitoring products to a world leading position.

stay one step ahead



Your first choice for Environmental Monitoring Solutions for Pharmaceutical Industry:
SigmaAldrich.com/environmentalmonitoring



Surface and
Personnel Monitoring

Eliminating blind spots

You can never be too cautious when it comes to keeping production plants clean.

To ensure that your hygiene and safety measures work, air sampling is often not enough. In order to stay on the safe side and avoid blind spots, monitoring surfaces and personnel is crucial. Thanks to our ready-to-use contact plates, slides and swabs, it's simple.

In the pharmaceutical production area a broad range of disinfectants are used and which may leave residues of their active ingredients on the surfaces. Therefore, culture media contain different neutralizers to inactivate disinfectant residues and facilitate the growth of microorganisms. Mainly four neutralizers are used for culture media, which are deployed for environmental monitoring: lecithin, Tween® 80, histidine and sodium thiosulfate.





ICR swabs

for surface and personnel monitoring in isolators and cleanrooms

Our ICR swabs are designed for absence-presence testing on dry surfaces that are difficult to access, and for personnel monitoring.

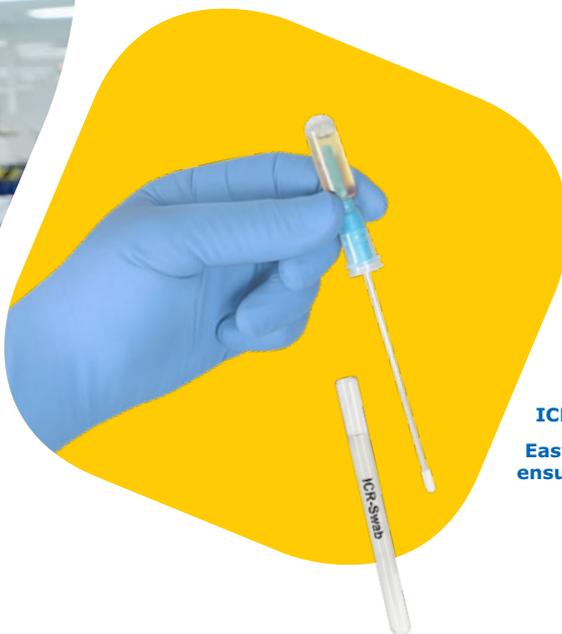
The snap valve design of the swab makes handling both convenient and safe. The swab tip material displays low abrasion, which minimizes the release of particles during use. The tip's moistening solution does not leave any growth promoting residues on the sampled surfaces.

The medium is TSB supplemented with neutralizers to ensure optimal growth conditions. It is supplemented with neutralizers according to pharmacopoeia recommendation. By default, it is supplemented to overcome growth inhibiting properties of VHP residues in isolators.

A **stainless steel rack** helps with the safe and easy transport of larger numbers of ICR Swabs. It holds 36 tubes at dimensions of 196 x 99 x 104 mm.

► **Ordering Information see page 26**

Learn more on
[SigmaAldrich.com/
icr-swab](https://SigmaAldrich.com/icr-swab)



**ICR swabs:
Easy handling
ensures safety**

ICR Contact Plates

for isolators and critical cleanrooms

Secure and reliable:

- Data matrix barcode on each plate: paperless and secure identification of individual plates
- Transparent, H₂O₂-impermeable triple-sleeve packaging: safe transportation in cleanrooms (ISO 5) and isolators
- Produced in cleanrooms, gamma-irradiated in final packaging: minimizes risk of contamination

Convenient:

- Storage at room temperature: storable at site of use
- Long shelf life: fewer incoming goods controls
- SDA in pink plates: minimizes risk of confusion / easily distinguishes between TSA and SDA

Flexible:

- Many different formulations for the monitoring of sanitized, dry surfaces
- Supplemented by neutralizers for a wide range of disinfectants



ICRplus
Contact plates



CLOSED- or
VENT-Closure

ICRplus Contact Plates

for isolators and critical cleanrooms

All the advantages of ICR Contact Plates ... and more:

- CLOSED- or VENT-Closure: safe transport and flexible incubation conditions (aerobe, anaerobe and microaerophilic).
- Supplemented by neutralizers for a wide range of disinfectants and β -lactam antibiotics
- New formulation of non-animal origin available: minimizing the risk of BSE contamination

Accessories for settle and contact plates

To further add to the ease of use and safety of our environmental monitoring solutions, we offer a variety of accessories that help you get the job done. To minimize cross-contamination caused by non-sterile handling of plates, use our sterilized zipper bags when you transfer samples from your production area to the incubators.

Stainless steel racks help with the safe and easy transport of larger numbers of contact and settle plates. It has a capacity for 10 contact plates at a size of 70 x 250 mm (height), the rack for settle plates also has a capacity for 10 plates at a size of 100 x 240 mm (height).



Learn more on
[SigmaAldrich.com/
contact-plates](https://www.sigmaaldrich.com/contact-plates)

Neutralizer A: Neutralization of antimicrobial activity

We offer a wide variety of formulations to counter the effects of the presence of a range of antimicrobial agents, such as disinfectant residues or β -lactam antibiotics on surfaces. With standard neutralizers such as lecithin, Tween® 80, histidine and sodium thiosulfate, a wide range of disinfectants can be neutralized reasonably effectively. However, residues of high concentrated quaternary ammonium compounds (QAC) as well as polyhexamethylene biguanides require higher neutralization capacity. For these purposes, we have developed the "Neutralizer A" mixture. It is capable of neutralizing all disinfectant residues tested so far.

Cephase media

In β -lactam antibiotic manufacturing sites, the sampling results of air and surface monitoring are at risk of being affected by residues of the antibiotic. The efficacy of different β -lactamases against the broad spectrum of β -lactam antibiotics varies and depends on their origin of isolation. Our Cephase media shows an impressively broad spectrum of inactivated β -lactam antibiotics including the following components of the table.

Active agents	TSA + LT	TSA + LTHTh	TSA + Neutralizer A
Isopropyl alcohol	•	•	•
Hydrogen peroxide	•	•	•
Peracetic acid	•	•	•
Phenolics	•	•	•
Sodium hypochlorite	•	•	•
Aldehydes	•	•	•
QAC	• ¹	• ¹	•
Polyhexamethylene biguanides	x	x	•

1) Depending on concentration

Antibiotic group	Confirmed activity of Cephase containing plates
Penicillins	ampicillin, mezlocillin, oxacillin, penicillin
Penicillins mixed with lactamase inhibitors	ampicillin/sulbactam, amoxicillin/clavulanic acid, piperacillin/tazobactam
Cephalosporins	cefexim, cefazolin, cefotaxime, ceftriaxone, cefuroxime, cefquinom, cefepim, cefoperazon, ceftiofur, ceftiofur, ceftiofur
Penems	meropenem, imipenem
Monobactams	aztreonam

HYCON® Contact Slides

for monitoring of curved surfaces and personnel

HYCON® Contact Slides are designed for monitoring flat and curved surfaces as well as personnel. Depending on whether you need them for critical or non-critical environments, they are available in standard single packaging or in a double-bagged, gamma-irradiated format.

Both Standard HYCON® Contact Slides and Gamma-irradiated HYCON® Contact Slides are rectangular in shape, providing a constant surface of 25 cm². Individual sealing of the primary packaging allows for the use of single Contact Slides to reduce waste. The slide body is slightly flexible to allow for efficient sampling of curved surfaces. The slides are equipped with a cover slide for closure after use, increasing safety during both transport and incubation.

Gamma-irradiated HYCON® Contact Slides

For use in critical environments, final gamma-irradiation at 16–27 kGy minimizes contamination risks. The irradiated slides come in transparent double-packaging which makes safe transfer through material locks into critical cleanrooms simple. The fact that each slide is sealed individually allows for safe observation on contamination of the closed slide even before opening.

Single-bagged contact plates for environmental monitoring in less critical areas

When it comes to monitoring less critical cleanroom areas, such as grade C and D, or non-specified environments, our single bagged room temperature contact plates are a tried and tested choice.



Learn more on
SigmaAldrich.com/hycon-slides





**Microbial
Air Monitoring**

SOMETHING in the air?

Comprehensive monitoring solutions

When monitoring cleanrooms and isolators, diligence is key. We offer a variety of easy-to-use solutions which help you ensure the highest hygiene standards in critical environments. We offer settle plates to complement our active air monitoring system. To make sure that results are not distorted by the presence of antimicrobial agents, reliable neutralizers are available. No matter which of our products you choose to help you keep contamination at bay, they all meet the international standards and regulations.

Environmental monitoring in isolators and cleanrooms: ICR and ICRplus

ICR and ICRplus settle plates are designed to meet the demands of environmental monitoring in isolators and cleanrooms. To reduce the percentage of water loss during air monitoring, the settle plates come with a high filling volume of 30 mL in 90 mm plates.

Animal-free formulations are available for minimizing the risk of BSE/TSE contamination. We offer Sabouraud Dextrose Agar formulations in pink plates in order to allow for clear and easy differentiation of TSA and SDA. Additionally, ICRplus products come with a sophisticated locking system for safe transport and optimized incubation conditions under different atmospheres.

ICR Settle Plates

for isolators and critical cleanrooms



Secure and reliable:

- Data matrix barcode on each plate: paperless and secure identification of individual plates
- Transparent, H₂O₂-impermeable triple-sleeve packaging: safe transportation in cleanrooms (ISO 5) and isolators
- Produced in cleanrooms, gamma-irradiated in final packaging: minimizes risk of contamination

Convenient:

- Storage at room temperature: storable at site of use
- Long shelf life: fewer incoming goods controls
- High filling volume settle plates: allow prolonged exposition and incubation
- SDA in pink plates: easily distinguishes between TSA and SDA

Flexible:

- Usable for personnel monitoring or as disposables for active air monitoring with MAS air samplers
- Supplemented by neutralizers for a wide range of disinfectants and β -lactam antibiotics
- New formulation of non-animal origin available: minimizing the risk of BSE contamination

Learn more on
[SigmaAldrich.com/
settle-plates](https://SigmaAldrich.com/settle-plates)



ICRplus Settle Plates

for isolators and critical cleanrooms

All the advantages of ICR Settle Plates...and more:

- CLOSED- or VENT-Closure: safe transport and flexible incubation conditions (aerobe, anaerobe and microaerophilic)
- Many different formulations available

Single-bagged settle plates for environmental monitoring in less critical areas

When it comes to monitoring less critical cleanroom areas, such as grade C and D, or non-specified environments, our single bagged long incubation settle plates are a tried and tested choice. Their high-filling volume – 30 mL in 90 mm settle plates – reduces the percentage of water loss during the air monitoring procedures.



**CLOSED- or
VENT-Closure**

MAS-100 NT[®] & MAS-100 NT[®] with Filter Air Samplers

The industry standard for viable air sampling

MAS-100 NT Ex[®] & MAS-100 NT Ex[®] with Filter Air Samplers

Explosion-proof air sampling

The Industry Standard for GMP Compliant Performance

The **MAS-100 NT[®]** and **MAS-100 NT Ex[®]** portable microbial air samplers are the industry standard for use in critical environments. These compact, yet sophisticated instruments are the preferred choice for the highest demands in microbial air monitoring, providing utmost accuracy and excellent, proven collection efficiency. Their low particle generation complies with the requirements of ISO 14644 for use within ISO 5 controlled environments.

- Third-party validation acc. ISO 14698 (complies with EN 17141) confirms a d50 value of <1 µm and an excellent biological efficiency
- Built-in air flow compensation guarantees precise, standardized and reproducible flow rates
- Suitable for ISO 5/GMP Grade A cleanrooms with minimized turbulence of unidirectional air flow
- Compatible with 90 mm Petri dishes, 55 mm contact plates or Growth Direct™ cassettes
- Automated calibration with MAS-100 Regulus[®] digital anemometer
- Suitable for disinfection with many industry-standard disinfectants and vaporized hydrogen peroxide
- Interfaces to several EM software systems for digital and 21 CFR Part 11 compliant user management

Technical specifications

Parameter	MAS-100 NT [®] sampler	MAS-100 NT Ex [®] sampler
Size: Body / Perforated lid	270 x Ø 109 x 170 mm (w. handle & lid) / Ø 109 x 32 mm	
Weight: Body / Perforated lid	2.4 kg with perforated lid / 0.19 kg	
Material: Body / Perforated lid	Anodized aluminum / anodized aluminum	
Flow rate	100 standard liters per minute (SLPM) ±2.5%	
Flow regulation	Mass flow sensor	
Default perforated lid	300 holes with Ø 0.6 mm (D50 value of 1.1 µm; impaction speed 19.7 m/s @100 SLPM)	
Sample volumes	10 to 2000 liters (pre-set: 50, 100, 250, 500 & 1000 L)	
Sample modes	Standard single sample, sequential sampling: 2 to 50 fractions, start delay configurable from 1 to 120 min	
Batteries	Rechargeable 6 cell Li-Ion (7.4 V; 6.9 Ah)	Rechargeable 2 cell Li-Ion (7.4 V; 2.5 Ah)
Battery capacity	Approx. 5.5 h (for 33.000 L)	Approx. 2 h (for 12.000 L)
Operating conditions	5 °C to 40 °C non-condensing relative humidity up to 2000 m above sea level	
ATEX Certification	N/A	⊠ II eG Ex ec IIC T4 Gc
Tripod mounting	1/4" and a 3/8" tripod screw (optional quick-change adapter)	

Learn more on
[SigmaAldrich.com/
 portable-air-samplers](https://SigmaAldrich.com/portable-air-samplers)



Request a demo on
[SigmaAldrich.com/
 em-pharma-info](https://SigmaAldrich.com/em-pharma-info)



left to right:
 MAS-100 NT[®], MAS-100 NT[®]
 with filter mounting kit
 and MAS-100 NT[®] with Filter

Manufactured by MBV AG, Switzerland,
www.mbv.ch, MBV. Air. Nothing else.

Easy-to-use

MAS-100 VF[®] Air Sampler

Top Collection Efficiency in a Compact Design

The MAS-100 VF[®] active air sampler is especially designed for controlled environments. It is a particularly light-weight and compact model amongst the portable and battery-operated MAS-100[®] microbial air samplers. Its simple user menu is easily accessed and operated by a single touch slide control. The instrument has the same flow rate, d50 value and impaction speed as the MAS-100 NT[®] sampler.

- Third-party validation acc. ISO 14698 (complies with EN 17141) confirms a d50 value of <1 µm and an excellent biological efficiency
- Suitable for ISO 5/GMP Grade A cleanrooms with minimized turbulence of unidirectional air flow
- Compatible with 90 mm Petri dishes, 55 mm contact plates or Growth Direct™ cassettes
- Integrated, pre-installed software can be operated on a standard web browser surface
- Automated calibration with MAS-100 Regulus[®] digital anemometer (calibration certificate stored within the instrument)



MAS-100 VF[®]

Manufactured by MBV AG,
Switzerland, www.mbv.ch,
MBV. Air. Nothing else.

Technical specifications

Feature	Specification
Size: Body / Perforated lid	179 x Ø 109 x 148 mm (w. handle) / Ø 109 x 32 mm
Weight: Body / Perforated lid	1.9 kg incl. perforated lid / 0.19 kg
Material: Body / Perforated lid	Anodized aluminum / anodized aluminum
Flow rate	100 liters per minute (LPM) ±4%
Flow regulation	Electronically
Default perforated lid	300 holes with Ø 0.6 mm (D50 value of 1.1 µm; impaction speed 19.7 m/s @100 LPM)
Sample volumes	10 to 2000 liters (pre-set: 50, 100, 250, 500 & 1000 L)
Sample modes	Standard single sample, start delay configurable from 1 to 120 min
Batteries	Rechargeable 6-cell Li-Ion battery (7.4 V/6.9 Ah)
Battery capacity	Approx. 5 h (for 30.000 L)
Operating conditions	5 °C to 40 °C non-condensing up to 2000 m above sea level
Tripod mounting	1/4" and a 3/8" tripod screw (optional quick-change adapter)



Learn more on
[SigmaAldrich.com/
MAS-100-VF](http://SigmaAldrich.com/MAS-100-VF)



Request a demo on
[SigmaAldrich.com/
em-pharma-info](http://SigmaAldrich.com/em-pharma-info)

MAS-100 Atmos®

Microbial compressed gas sampler

The instrument is designed to collect microorganisms in compressed gases by gentle but direct impaction onto agar. The impaction is performed under pressure to prevent any harm to microorganisms caused by fast dynamic decompression. The impaction speed at a default flow rate of 100 LPM is identical to all other MAS-100® air samplers and provides a nominal d50 of 1.1 µm.

Automatic detection of pressure and a mass flow sensor ensure secure, accurate sampling of compressed gases. Four gas types (Ar, N₂, air and CO₂) are pre-programmed and easily accessible. The instrument is also designed to operate at lower pressure. This new level of automation minimizes risk and makes sampling compressed gas much easier.

- Easy to handle
- Automated flow rate regulation and decompression avoids human errors
- Validated accuracy of gas amounts for selectable gas types and pressure range
- 21 CFR Part 11 compliant software



Learn more on
[EMDMillipore.com/
MAS-100-CG-EX](https://EMDMillipore.com/MAS-100-CG-EX)

Technical specifications

Feature	Specification
Size: Body / Perforated lid	180 x 210 x 500 mm (with handle) / Ø 109 x 90 mm
Weight: Body / Perforated lid	7.3 kg / 0.75 kg
Material: Body / Perforated lid	Injection-molded high-performance polystyrene / anodized aluminum
Gas types (selectable, validated for correct sample volumes)	Compressed air, nitrogen (N ₂), carbon dioxide (CO ₂), argon (Ar)
Pressure range	1.2 to 7 bar abs (17.4 to 101.5 psi abs)
Default perforated lid	300 holes with Ø 0.6 mm (100 LPM: D50 1.1 µm; impaction speed 19.7 m/s or 50 LPM: D50 1.6 µm; impaction speed 9.8 m/s)
Sample volumes	50 to 3000 normal liters (NL)
Batteries	Li-Ion battery (7.2 V; 9.6 Ah, 72 Wh)
Battery capacity	2 h to 5 h (depending on gas type & pressure range); default battery indicator: 30 x 1000 liters at 2 bar abs for compressed air - increased number of samples at increasing pressure and lower volumes
Operating conditions	5 °C to 45 °C non-condensing up to 3000 m above sea level

► **Ordering Information see page 29**



Find out more about
our latest innovation:
[SigmaAldrich.com/
mas-atmos](https://SigmaAldrich.com/mas-atmos)



MAS-100 Atmos®
Microbial compressed
gas sampler



Isolators
and RABS

All eyes on your process

Clever solutions for isolators and RABS

Specific environments such as isolators and RABS are designed to prevent any human contact during your controlled manufacturing. These barrier technologies have highly sophisticated requirements for the instrumentation and culture media.

The main requirements for microbial air samplers and culture media are the prevention of cross-contamination, saving space and the reduction of time consuming transfer of products into the controlled manufacturing areas.

The MAS-100 Iso NT® & MAS-100 Iso MH® instruments allow a safe remote microbial air sampling in perfect combination with the IsoBag® for rapid culture media transfer into isolators.



MAS-100 Iso MH[®] & MAS-100 Iso NT[®] Air Samplers

Remote Sampling for Isolators and RABS

The **MAS-100 Iso MH[®]** air sampler is used to monitor microbiological contamination of the air in isolators or RABS remotely. Per control unit it allows the installation of up to four sampling heads for standard 90-100 mm Petri dishes at critical control points. All electronic and moving parts are kept outside the critical zone.

All instruments are delivered with standard interfaces (USB, RS232, and digital I/O). Models with additional interfaces such as Ethernet, Profibus or Profinet are available optionally for connectivity with computer and/or programmable logic controllers used in isolators.

- Double valve system to prevent back-flow and cross-contamination
- Active VHP decontamination of air duct
- Up to 10 m distance between sample location and control unit in isolators (50 m without using VHP decontamination)
- Third-party validation acc. ISO 14698 (complies with EN 17141) confirms a d50 value of <1 µm and an excellent biological efficiency
- Built-in air flow compensation for precise, reproducible flow rate of 100 SLPM
- Various stainless steel sampling head configurations for 90 mm plates or other plate formats (e.g. Growth Direct[™] plates)
- Multiple options for combining filters (in-line/exhaust)
- Automated calibration with MAS-100 Regulus[®] digital anemometer

► **Ordering Information see page 30**



Learn more on
[SigmaAldrich.com/
isolator-air-sampling](https://SigmaAldrich.com/isolator-air-sampling)



Request a demo on
[SigmaAldrich.com/
em-pharma-info](https://SigmaAldrich.com/em-pharma-info)





The **MAS-100 Iso NT**[®] shares most of its features with the MAS-100 Iso MH[®] sampler but is designed for one sampling location only. It also is additionally equipped with an alpha numerical display.



Technical specifications

Parameter	MAS-100 Iso MH/NT [®] sampler
Size: Body (MH / NT)	160 x 423 x 380 mm / 160 x 283 x 230 mm
Weight: Body (MH / NT)	9.1 to 16.6 kg (depending on configuration) / 7.3 kg
Material: Body (MH / NT)	Powder coated / Walls from anodized aluminum and body from stainless steel
Size: Sampling Head	Ø 109 x 900 mm (Connector Tri-Clamp, Ø 50.5 mm)
Weight: Sampling Head	1.5 kg
Material: Sampling head	Stainless Steel EN 1.4435 (X2CrNiMo18-14-3), acc. BN2 (electro polished pharmaceutical quality)
Flow rates	100 SLPM ±2.5%
Flow regulation	Mass flow sensor
Default perforated lid	300 holes with Ø 0.6 mm (@100 SLPM: D50 1.1 µm; impaction speed 19.7 m/s)
Sample volumes	1 to 2000 liters (pre-set: 50, 100, 250, 500 & 1000 L)
Sample modes	Standard single sample, sequential sampling: 2 to 50 fractions, start delay configurable from 1 to 120 min; in addition, the MAS-100 MH [®] sampler offers consecutive sampling mode (CNS)
Power supply	110-240 V AC, 0.7-1.5 A / 47-63 Hz
Power input of instrument	24 V DC ±5%, max. limits: 2.7 A and 65 W
Operating conditions	5 °C to 40 °C (non-condensing relative humidity); up to 2000 m above sea level

► **Ordering Information see page 30**

Request a demo on
SigmaAldrich.com/em-pharma-info



IsoBag[®] rapid transfer bag

A true timesaver

Production workflows are always at their most efficient when you have all your tools ready and available. Which is why we created a unique transportation and packaging bag as a reliable and easy way to have environmental monitoring plates right at hand in the isolator: the IsoBag[®] rapid transfer bag.

Environmental monitoring in aseptic production isolators is made quicker by the IsoBag[®] as it provides ready-to-use gamma-irradiated contact or settle plates for immediate use; the bag is simply mounted to the 190 mm alpha port of the isolator and the required amount of plates can be transferred into the isolator for immediate environmental monitoring. Saving time for decontamination will increase your operational productivity. In addition, no extra space is required in your isolator to store the required amount of plates between decontamination cycles.

► **Ordering Information see page 31**

- Simple, safe and convenient plate transfer in operation
- Easy adjustment of monitoring needs during campaigns
- Gain isolator space by externalizing plate storage
- Available with wide variety of ICR and ICRplus contact or settle plates



Learn more no
SigmaAldrich.com/isobags



Media Fill / Aseptic Process Simulation

YOUR GOAL IS ZERO POSITIVES. SO IS OURS.

Granulated and ready-to-use culture media for secure media fill tests

Every aseptic process should be validated with at least three successful aseptic process simulations, or media fill tests. The aseptic process simulation should then be repeated on a regular basis. The choice of the media for aseptic process simulation is crucial. You want to make sure:

- that you have the right media to mimic the product, depending if you have solid to liquid or liquid to liquid filling line.
- that the media won't bring any contamination to your aseptic process line.
- that the technical performances of the media allows you to handle it like your product: it must be cold filterable.
- that the microbiological performance of the media enables to detect any contamination in your production line. Our media fill range overcomes all these critical challenges.

Granulated and ready-to-use culture media

for secure media fill tests

When performing media fill trials, you shouldn't have to worry about culture media compromising your validated process.

With our irradiated, triple-wrapped culture media, you won't. Every batch is carefully tested.

Choice of format for your simulation:

- Sterile ready-to-use broths in gas-impermeable 10 L bags
- Low-dust granules with excellent cold-filterability performance

Choice of media type:

- Tryptic soy broth or thioglycolate broth
- Vegetable peptone alternatives for TSB and FTM

Ultimate security:

- Validated sterilization and irradiation processes

► **Ordering Information see page 31**

TSB 5 kg irradiated
and 10 L bag Ready-To-Use



Learn more on
[SigmaAldrich.com/
mediafills](https://SigmaAldrich.com/mediafills)



Services

our services for you

Benefit from our all-around services offer from validation and training to maintenance and calibration.

Validation package: validation protocols and on-site IQ/OQ service

We aim to provide complete validation documentation to help you through the validation process. Our validation protocols are based on our internal product qualification test methods. These extensive protocols will enable the QA/QC Lab to quickly initiate your validation master plan and perform IQ, OQ and PQ (suitability of the test methodology) with ease. International guidelines such as EP/USP and GMP are followed rigorously.

Our experienced and trained validation engineers are skilled to assist in validation protocol implementation within the QC microbiology laboratory, so the QA/QC departments do not have to allocate resources. A basic technical training on your air sampler is also provided during the validation engineer's visit. Having our validation protocol and on-site IQ/OQ service eliminates high costs, both apparent and hidden, and helps ensure the validation is completed quickly and economically, and guarantees optimal performance over the equipment lifetime. We also provide Advanced Operator Training at your site. Contact your local sales representative for the availability of validation support and training at your site.

Service plans: preventative & curative maintenance

The services provided include:

- Complete yearly visual, functional and performance "as found" and "as left" checks including calibration for all MAS-100® systems.
- Calibration certificate with traceability to referenced standard and complete performance report is provided with every service. In addition to the above services, additional verification, calibration or preventive maintenance (included verification & calibration) options are available. We offer several service plans levels to give you the possibility to enhance the coverage of the equipment e.g. spare part and repair visits can be included in your contract. Our certified service engineers can service your air sampler in our closest repair depot or directly in your lab. Contact your local sales representative for more information.



Traceability & calibration accuracy

The sample collection volume for each MAS-100® System is measured and adjusted with the dedicated anemometer system that is using a specific calibration station, which is directly traceable to standards. Traceability relies on a documented unbroken chain of calibrations linking measurements made to referenced standard. The uncertainty (accuracy) of a measurement is determined by the combined uncertainties of all measurements made by devices between the referenced standard and the device being calibrated, this is called the “chain of comparisons”. With each link in the chain, additive uncertainty occurs. To minimize uncertainty and maintain accuracy the number of links in the chain of comparison must be minimized and the uncertainty for each link must be documented. You can have the confidence when monitoring critical environments that every sample volume collected is accurate.



For more information or a quotation on our services portfolio please contact your local sales representative or visit our website at:

SigmaAldrich.com/EM-services

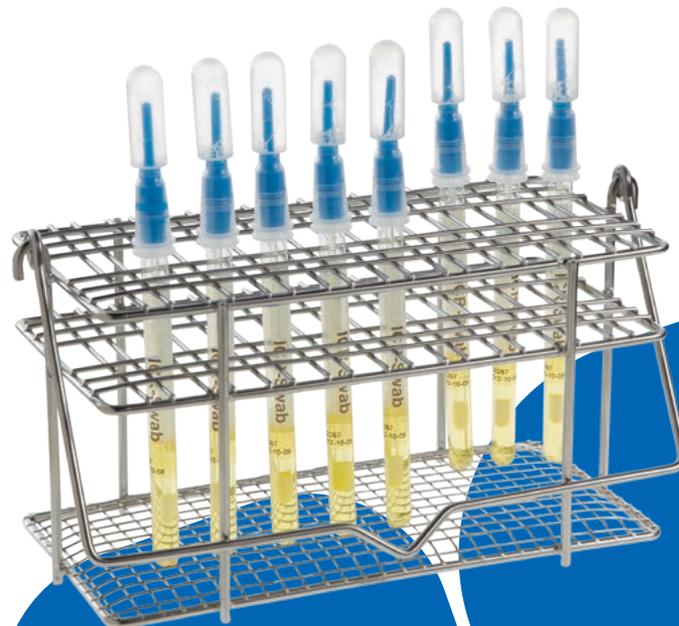


Surface & Personnel Monitoring

Ordering information

Description	Qty.	Ord. No.
Swabs		
ICR swab	100	1.46529.0100
Accessories		
Swab Rack (stainless steel)	1	1.46530.0001
55 mm Contact Plates (triple bagged, gamma-irradiated, non-lockable)		
SDA Contact +LTHTh – ICR (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate, filled in pink plates)	20 200	1.46201.0020 1.46201.0200
TSA Contact +LT – ICR (with neutralizers lecithin, Tween® 80)	20 200	1.46195.0020 1.46195.0200
TSA LTHThio cont. ICR (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 200	1.46797.0020 1.46797.0200
TSA Contact +LTHTh – ICR (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 200	1.46231.0020 1.46231.0200
55 mm Contact Plates (triple bagged, gamma-irradiated, lockable)		
Chocolate Contact Agar +LTH – ICR+ (with neutralizers lecithin, Tween® 80, histidine, supports growth of fastidious aerobic and anaerobic microorganisms)	20	1.46555.0020
SDA Contact +LTHTh – ICR+ (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate; filled in pink plates)	20 200	1.46501.0020 1.46501.0200
SDA Contact +LTHTh selective – ICR+ (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate, irradiation-resistant antibiotics to inhibit bacterial growth, filled in pink plates)	20 200	1.46538.0020 1.46538.0200
TSA Contact +LT – ICR+ (with neutralizers lecithin, Tween® 80)	20 200	1.46552.0020 1.46552.0200
TSA with LTHThio cont. – ICR+ (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 200	1.46783.0020 1.46783.0200
TSA Contact +LT+ Cephas – ICR+ (with neutralizers lecithin, Tween® 80, β-lactamses for inactivation of penicillins, all generations of cephalosporins and carbapenems)	200	1.46539.0200
TSA with Penase LTHThio cont. ICR+ (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate, penase for inactivation of penicillins)	20 200	1.46798.0020 1.46798.0200
Vegetable pepton agar LTHThio cont. ICR+ (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 200	1.46803.0020 1.46803.0200
Neutralizer A – Contact – ICR+ (neutralizers for increased spectrum of sanitizers)	20 200	1.46697.0020 1.46697.0200
55 mm Contact Plates (single bagged, lockable and non-lockable)		
SDA Contact+ Chloramphenicol – RT+ (lockable plate)	20	1.46549.0020
TSA Contact – RT	20	1.46240.0020
TSA Contact +LTH – RT (with neutralizers lecithin, Tween® 80, histidine)	20	1.46200.0020
TSA Contact +LTH – RT+ (with neutralizers lecithin, Tween® 80, histidine, lockable plate)	20	1.46554.0020
Accessories		
Plate Rack for contact plates (stainless steel rack for 10 x 55 mm plates)	1	1.46502.0001

Description	Qty.	Ord. No.
HYCON® Contact Slides (gamma-irradiated)		
Contact Slides TC-y	20	1.44022.0020
Gamma-irradiated Tryptic Soy Agar, double wrapped; for determination of total count in aseptic environment; with neutralizers (lecithine, sorbitol monooleate complex, Tween® 80) and growth supplements.	100	1.44022.0100
Contact Slides DE-y	20	1.44021.0020
Gamma-irradiated, modified Dey Engley Agar (D/E Agar), double-wrapped; for determination of total count in aseptic environments; with neutralizers (lecithin, sorbitol monooleate complex, sodium thioglycolate, sodiumbisulfite) and growth supplements.		
Contact Slides PEN-y	100	1.44014.0100
Gamma-irradiated Tryptic Soy Agar with Penase, double-wrapped; for determination of total count in penicillin-containing air; with neutralizers (lecithin, L-histidine, sorbitol monooleate complex, Tween® 80) and growth supplements.		
Contact Slides LAC-y	100	1.44015.0100
Gamma-irradiated Tryptic Soy Agar with penase and a broad-spectrum cephalosporinase, double-wrapped; for determination of total count in environments with antibiotics contaminating air; with neutralizers (lecithin, L-histidine, sorbitol monooleate complex, Tween® 80) and growth supplements.		
Contact Slides SDX-y	20	1.44016.0020
Gamma-irradiated Sabouraud Dextrose Agar with modified pharmacopoeia formulation, double-wrapped; for determination of yeasts and molds in aseptic environments; with neutralizers (Tween® 80, L-a-phosphatidylcholine) and growth supplements.		
HYCON® Contact Slides (single bagged)		
Contact Slides TC	20	1.44023.0020
Tryptic Soy Agar; for determination of the total count; with neutralizers (lecithin, L-histidine, sorbitol monooleate complex, Tween® 80) and growth supplements.	100	1.44023.0100
Contact Slides YM	20	1.44018.0020
Rose Bengal Agar with streptomycin and chloramphenicol; for determination of yeasts and molds; with growth supplements.		
Contact Slides SDX	20	1.44017.0020
Sabouraud Dextrose Agar with modified pharmacopoeia formulation; for determination of yeasts and molds; with neutralizers (Tween® 80, L-a-phosphatidylcholine) and growth supplements.		
Contact Slides C	20	1.44019.0020
Mac Conkey Agar; for determination of coliform bacteria; with growth supplements.		



Swab Rack
stainless steel
(Ord. No. 1.46530.0001)



Microbial Air Monitoring

Ordering information

Description	Qty.	Ord. No.
90 mm Settle Plates (triple bagged, gamma-irradiated, non-lockable)		
SDA +LT – ICR 30 mL (with neutralizers lecithin, Tween® 80, filled in pink plates)	120	1.46081.0120
SDA +LTHTh – ICR 30 mL (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate, filled in pink plates)	20 120	1.46005.0020 1.46005.0120
SDA selective +LTHTh – 30 mL ICR (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate, antibiotics against bacteria, filled in pink plates)	120	1.46016.0120
TSA – ICR 30 mL	20 120	1.46001.0020 1.46001.0120
TSA +LT – ICR 30 mL (with neutralizers lecithin, Tween® 80)	20 120	1.46050.0020 1.46050.0120
TSA +LTHThio sedi. ICR (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 120	1.46786.0020 1.46786.0120
TSA +LT+ Cephase – ICR (with neutralizers lecithin, Tween® 80, β-lactamases for inactivation of penicillins, all generations of cephalosporins and carbapenems)	20 120	1.46076.0020 1.46076.0120
TSA w. Penase LTHThio sedi. ICR (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate, penase for inactivation of penicillins)	20 120	1.46799.0020 1.46799.0120
150 mm Settle Plates		
TSA LTHThio sedi. ICR 150 mm (3 plates, each triple-packed – with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	18	1.46820.0018
90 mm Settle Plates (triple bagged, gamma-irradiated, lockable)		
TSA + LTHThio sedi. ICR+ (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 120	1.46787.0020 1.46787.0120
TSA +LT 90 mm ICR+ (with neutralizers lecithin, Tween® 80)	20 120	1.46684.0020 1.46684.0120
TSA 90 mm ICR+	20 120	1.46685.0020 1.46685.0120
TSA +LT +Cephase-ICR+ 90 mm (with neutralizers lecithin, Tween® 80)	120	1.46700.0120
TSA w. Penase LTHThio sedi. ICR+ (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 120	1.46800.0020 1.46800.0120
SDA +LTHTh-ICR+ 90 mm (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 120	1.46702.0020 1.46702.0120
Veg. Pept. Agar w. LTHThio sedi.-ICR+ (with neutralizers lecithin, Tween® 80, histidin, sodium thiosulfate)	20 120	1.46804.0020 1.46804.0120
90 mm Settle Plates (single bagged, non-lockable)		
SDA – LI acc. EP	20 120	1.46028.0020 1.46028.0120
SDA + Chloramphenicol – LI 30 mL	20 120	1.46003.0020 1.46003.0120
SDA +LTHTh – LI 30 mL (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 120	1.46052.0020 1.46052.0120
TSA – LI 30 mL EP+USP	20 120	1.46004.0020 1.46004.0120
TSA +LTHTh – LI 30 mL (with neutralizers lecithin, Tween® 80, histidine, sodium thiosulfate)	20 120	1.46002.0020 1.46002.0120

Description	Ord. No.
MAS-100® portable Microbial Air Samplers	
MAS-100 NT® air sampler (1 unit in hard carrying case, battery, 300-hole perforated lid, dust cover, mains charger, USB cable, 3 mm allen key, and USB stick with all documentation)	1 09191.0001
MAS-100 NT® with Filter air sampler (1 unit in hard carrying case, battery, 300-hole perforated lid, dust cover, mains charger, USB cable, 3 mm allen key, and USB stick with all documentation)	1.17274.0001
MAS-100 NT Ex® air sampler, explosion proof (1 unit in hard carrying case, battery, 300-hole perforated lid, dust cover, mains charger, USB cable, 3 mm allen key, and USB stick with all documentation)	1.09194.0001
MAS-100 NT Ex® with Filter air sampler, explosion proof (1 unit in hard carrying case, battery, 300-hole perforated lid, dust cover, mains charger, USB cable, 3 mm allen key, and USB stick with all documentation)	1.17275.0001
MAS-100 VF® (1 unit in hard carrying case, battery, 300-hole perforated lid, dust cover, mains charger, USB cable, 3 mm allen key, and USB stick with all documentation)	1.17103.0001
MAS-100® Regulus (digital Anemometer for automatic calibration of MAS-100® Air Samplers except MAS-100 Atmos®)	1.19153.0001
Accessories portable MAS-100® Microbial Air Samplers	
MAS-100 NT® Dust Cover, aluminum	1.09084.0001
MAS-100 NT® Perforated Lid, aluminum, 300-hole	1.09195.0001
MAS-100 NT® Perforated Lid, aluminum, 400-hole	1.09088.0001
MAS-100 NT® Perforated Lid, aluminum, 300-hole, edge protected	1.19363.0001
MAS-100 NT® Perforated Lid, aluminum, 400-hole, edge protected	1.19364.0001
Contact Plate Adapter (not necessary for MAS-100 VF®)	1.09214.0001
Perforated lid aluminum 400 x 0.7 mm for non-lockable contact plates	1.09213.0001
Perforated lid aluminum 300 x 0.6 mm for lockable and non-lockable contact plates	1.19149.0001
Perforated lid with clamps, aluminum 300 x 0.6 mm (compatible with Growth Direct™)	1.17316.0001
Perforated lid without clamps, aluminum 300 x 0.6 mm (compatible with Growth Direct™)	1.17315.0001
Tripod	1.09326.0001
Quick Adaptor for Tripod (not suitable for MAS-100 Eco®)	1.09223.0001
Mounting Kit for Filter (for MAS-100 NT®/NT Ex® including HEPA H13 filter)	1.17276.0001
HEPA H13 Filter 74 mm (for MAS-100 NT®/NT Ex® with filter or with filter mounting kit)	1.17278.0001
MAS-100® Tube Adaptor (not suitable for MAS-100 Eco®)	1.09224.0001
MAS-100 NT® Mains Charger with LEMO plug (fits to all versions MAS-100 NT®/NT Ex®)	1.09200.0001
MAS-100 NT® Mains Charger with DC plug (compatible with serial numbers > 110500)	119133
MAS-100 VF® Power supply	1.17104.0001
Compressed Gas Testing	
MAS-100 Atmos® gas sampler, standard microbial compressed gas sampler	1.17328.0001
Sampling head Atmos® gas sampler with perforated lid 300 x 0.6 mm, provides D50 of 1.1 µm at 100 liters/min	1.17357.0001
Sampling head Atmos® gas sampler with perforated lid 300 x 0.47 mm, provides D50 of 1.1 µm at 50 liters/min	1.17363.0001
Pressure tube Atmos gas sampler 2 m with TC Connector, PTFE Tube with 3/8" female connector to gas supply with connector to instrument	1.17354.0001
Gas exhaust tube Atmos® gas sampler 5 m with TC Connector, PVC tube Ø 50 mm, stainless steel connector and tri-clamp	1.17349.0001
Adapter gas exhaust tube for MAS-100 Atmos® gas sampler, stainless steel adapter for self-assembly of gas exhaust tubing (tubing excluded)	1.17348.0001
Hardware key set (5x) for MAS-100 Atmos® gas sampler, re-writable for individual user login	1.17333.0001
Wheeled transport case for MAS-100 Atmos® gas sampler for safe transportation	1.17334.0001
Dust cover for MAS-100 Atmos® gas sampler, polypropylene, white, autoclavable	1.17340.0001
Plate holder for MAS-100 Atmos® gas sampler stainless steel, autoclavable	1.17335.0001
Filter cover for MAS-100 Atmos® gas sampler with 3 screws, aluminum, autoclavable	1.17336.0001
HEPA H13 replacement filter, Ø 74 mm; filter efficiency H13	1.17278.0001
MAS-100 Atmos® Battery Charger for MAS-100 Atmos(R) including country specific power plugs	1.17329.0001
Digital Validation Protocols to be completed by On-Site IQ & OQ Service	
MAS-100 VF® Validation Protocol	MAVFIQOQEP
MAS-100 NT® Validation Protocol	MANTIQOQEP
MAS-100 Atmos® Validation Protocol	MATMIQOQEP

Note: The 300-hole perforated lid is compatible with legacy systems, but a specific calibration is required.

Control units for MAS-100® Iso MH® air samplers

Description Control Unit	Standard Interface USB	Standard Interface USB + Ethernet	Standard Interface USB + Profibus	Standard Interface USB + Profinet
MAS-100 Iso NT® air sampler	1.09168.0001	1.09174.0001	1.09173.0001	*1.17291.0001
MAS-100 Iso MH® air sampler - One head	*1.17174.0001	*1.17178.0001	*1.17177.0001	*1.17292.0001
MAS-100 Iso MH® air sampler - Two heads	*1.17118.0001	*1.17145.0001	*1.17144.0001	*1.17309.0001
MAS-100 Iso MH® air sampler - Three heads	*1.17146.0001	*1.17148.0001	*1.17147.0001	*1.17310.0001
MAS-100 Iso MH® air sampler - Four heads	*1.17149.0001	*1.17157.0001	*1.17155.0001	*1.17312.0001

*MTO products are not in stock – please mind lead times

Accessories for MAS-100 Iso NT® & MAS-100 Iso MH® air samplers

Product	Description	Ord. No.	MAS-100 Iso MH®	MAS-100 Iso NT®
Perforated lid	300 holes w. Ø 0.6 mm, edge-protected, stainless steel (default version)	1.09189.0001	✓	✓
Perforated lid	400 holes w. Ø 0.7 mm, edge-protected, stainless steel	1.09222.0001	✓	✓
Standard base for sampling head	Stainless steel with Allen key, tri-clamp, and silicone gasket	1.09328.0001	✓	✓
Silicone gasket (5x)	Sealing between standard base and tubing	1.17084.0001	✓	✓
Easy clean base for sampling head	Stainless steel with tri-clamp and silicone screen gasket	1.17091.0001	✓	✓
Silicone screen gasket (5x)	Sealing between easy clean base models and tubing	1.17099.0001	✓	✓
*RapidMicroBio easy clean base	Stainless steel, for GD cassettes	1.17319.0001	✓	✓
*RapidMicroBio perforated lid	300 holes x 0.6 mm, stainless steel for GD cassettes	1.17314.0001	✓	✓
Dust cover	Stainless steel cover protects sieve from dirt	1.09644.0001	✓	✓
Tri-clamp (3x)	To facilitate mounting of sampling heads	1.09440.0001	✓	✓
Elbow joint	Stainless steel with 2 tri-clamps and silicone gaskets	1.17083.0001	✓	✓
Remote cable MAS-100 Iso NT® air sampler	Can be used for remote start & stop of sampling and can display the instrument status via LED	1.17181.0001	✓	✓
Pressure test kit	For testing tightness of installation	1.17085.0001	✓	✓
*MAS-100 Iso NT® air sampler IP54 Kit	Protection against solid objects that are bigger than 1 mm and water splashing from any direction	1.17159.0001	–	✓
Power supply	For MAS-100 Iso NT® air sampler with power cord and regional plug adapters	1.17182.0001	–	✓
Power supply	For MAS-100 Iso MH® air sampler with power cord and regional plug adapters	1.09784.0001	✓	–
*Profinet module	Converts Profibus to Profinet interface	1.17290.0001	✓	✓
Opticap® XL Aervent® (3 pieces)	Hydrophobic 0.2 µm, length 4''	KTGRA04TT3	✓	✓
Opticap® XL5 Aervent® KTGR	Hydrophobic 0.2 µm, length 5''	KTGRA05TT1	✓	✓
Opticap® XL10 Aervent® KTGR	Hydrophobic 0.2 µm, length 10''	KTGRA10TT1	✓	✓

Description	Ord. No.
Digital Validation Protocols to be completed by On-Site IQ & OQ Service	
MAS-100 ISO NT ® Validation Protocol	MAISIQQEP
MAS-100 ISO MH ® Validation Protocol	MAMHIQQEP
IsoBag® rapid transfer bag	
IsoBag ® TSA+LT Contact for 190 mm alpha-port 10 x 10 Contact Plates 146195, 55 mm irradiated	1.46784.0100
IsoBag ® TSA+LTHT Contact for 190 mm alpha-port; 55 mm Contact Plates 146231, irradiated	1.46754.0100
IsoBag ® TSA+LTHTthio Contact+ for 190 mm alpha-port lockable 55 mm Contact Plates 146783, irradiated	1.46753.0100
IsoBag ® TSA+LT Settle+ for 190 mm alpha-port 8 x 10 lockable Settle Plates 146684, irradiated	1.46785.0080
IsoBag ® TSA+LTHTth Settle for 190 mm alpha-port 90 mm Settle Plates 146069, irradiated	1.46756.0080
IsoBag ® TSA+LTHTth Settle+ for 190 mm alpha-port 90 mm lockable Settle Plates 146683, irradiated	1.46755.0080
IsoBag ® TSA Settle for 190 mm alpha-port; 90 mm Settle Plates 146001, irradiated	1.46814.0080
IsoBag ® TSA+LT contact+ for 190 mm alpha-port; 55 mm lockable Contact Plates 146552, irradiated	1.46817.0100



IsoBag®
rapid transfer bag



Media Fill / Aseptic Process Simulation

Ordering information

Description	Granulated	Ready-to-use	Package Size	Ordering No.
Tryptic soy broth irradiated	•		500 g	1.00800.0500
			5 kg	1.00800.5000
Tryptic soy broth non-animal, irradiated	•		500 g	1.00550.0500
			5 kg	1.00550.5000
Tryptic soy broth non-animal, Halal, irradiated	•		500 g	1.02754.0500
			5 kg	1.02754.5000
Tryptic soy broth (in self-collapsing, single-use bag)		•	10 L	1.46316.0001
Vegetable peptone broth (in self-collapsing, single-use bag)		•	10 L	1.46332.0001
Vegetable peptone Broth (in self-collapsing, single-use bag) with Lynx aseptic connector		•	10 L	1.46749.0001
Thioglycolate broth, non-animal, irradiated	•		5 kg	1.08720.5000

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