



# ENVIRONMENTAL MONITORING, STERILITY CONTROL & ASEPTIC SOLUTIONS

TO BE COMPLIANT WITH

**ANNEX I PIC/S PE010-4**

**EU GMP Guide & EN/ISO 14644**





# ENVIRONMENTAL MONITORING

## SETTLE & CONTACT PLATES

Pharma Media Dr. Müller Culture Media are of the highest quality, produced under strict pharmaceutical grade conditions, dedicated to environmental microbiological control of grade A/B (including isolators) and C/D clean rooms. We offer multiple media for sampling Surface, Air, Water, Personnel (fingerprints) and Product.



**Features:**

- Safe transport and handling with lockable plates (Click & Safe)
- Long shelf life (minimum 9 months at delivery, 12 months at production)
- Room temperature storage (15-25°C)
- Temperature controlled delivery
- Long incubation without cracking
- Large batches = fewer incoming goods controls
- Unique identification number & data matrix code on each plate



### Contact plates

Item no.	Product description	Pack size
PMM.100.0100	TSA+ Neutralisers : Lecithin, Tween, Histidine, Thio-sulphate CSG*	10x10plates
PMM.300.0120	TSA+ Neutralisers: Lecithin, Tween, Histidine, Thiosulphate CS**	12x10plates
PMM.120.0100	SDA+ Neutralisers: Lecithin, Tween, Histidine, Thiosulphate CSG*	10x10plates

### Settle plates

Item no.	Product description	Pack size
PMM.200.0060	TSA+ Neutraliser : Lecithin, Tween, Histidine, Thiosulphate CSG*	6x10 plates
PMM.400.0060	TSA+Neutraliser : Lecithin, Tween, Histidine, Thiosulphate CS**	6x10 plates
PMM.220.0060	SDA+ Neutraliser : Lecithin, Tween, Histidine, Thiosulphate CSG*	6x10 plates

\* **CSG (Click & Safe Gamma)** : triple bagged, H2O2 impermeable foil, gamma-irradiated plates. For use in critical environments like clean room class A and B, isolators and RABs

\*\* **CS (Click & Safe)** : single bagged, for use in less critical environments like clean room class C and D

\*\*\* **Neutralisers** are being used for the inactivation of residues of disinfectants



Contact us for the total list of available products.

## AIRWEL® BIO-COLLECTORS

### Accelerate your microbiological air sampling

#### Standard features:

- Compatible with Petri dishes of 90 mm or 55 mm
- Air flow: 100 L/min or 200 L/min
- Compliant EU GMP/GLP, USP797/USP116, ISO14698/ISO17141/ISO17025
- Battery autonomy: 30 000 L
- Light and Compact: 1.6 kg
- Fully hermetic: IP65 dust and water protection
- Type of heads: Stainless steel or Disposable polyester
- Traceability via Bluetooth module - PC software and Android application
- Annual calibration service

#### Additional features for AIRWEL® +

- Compliant 21 CFR part 11
- Cascade password
- Full traceability via barcode scan (user, location, sample)
- Wireless induction charger
- Auto-test option



## BIOcontact L21 - CONTACT PLATE APPLICATOR

According **NF EN 17141:2020** the surface sampling can be carried out by applying an agar contained in a contact plate and that it "can be applied to the surface **for a few seconds at a uniform and regular pressure preventing any movement**". BIOcontact L21 allows repeatable and reproducible surface sampling.



#### Features:

- Sampling time: 10 sec +/- 1 sec
- Press strength: 500 or 600 g (on demand)
- Indicator light during sampling then signals the end of sampling by vibration
- Custom-made piston to adapt to your 55 mm contact plates
- Highly resistant to shocks and most detergents

## PETRIDISH RACKS

PetriPile® ensures safe handling, carrying and storage of petri dishes. Different sizes are available.

#### Features:

- Compliant with the use according to Good Laboratory Practice (GLP)
- Autoclavable
- Stackable
- Ergonomic handles
- Traceability via the writing area on the front
- Large range for Ø 55 mm, Ø 65 mm, Ø 90 mm and Ø 150 mm Petri dishes



**Contact us for the total list of available products.**

# STERILITY CONTROL & MEDIA FILL TEST

## | BOTTLED CULTURE MEDIA

The Aseptic Simulation Test, also called Media Fill Test, is a microbiological test that simulates the normal manufacturing conditions of a sterile product by replacing the pharmaceutical product with a culture medium. It is used to demonstrate control of the aseptic process and its environment. Pharma Media Dr. Müller bottled media are designed with safety features as well as convenience for handling in mind.

**Features:**

- Unique identification number and data matrix code on each bottle
- Autoclaving indicator on every bottle
- Packaged to minimize bioburden
- Several colors and sizes available
- Screw cap bottles and Infusion bottles with flip-off caps



### Bottled media for aerobic bacteria testing

Item reference	Product description	Pack size
PMM.500.B090	TSB, screw cap 90 ml bottle	12 bottles
PMM.500.B100	TSB, screw cap 100 ml bottle	12 bottles
PMM.503.B200	TSB, screw cap 200 ml bottle	12 bottles
PMM.505.D000	TSB, screw cap 1000 ml bottle	6 bottles
PMM.520.S100	TSB, flip cap* 100 ml bottle	20 bottles

### Bottled media for anaerobic bacteria testing

Item reference	Product description	Pack size
PMM.528.S100	FTM clear, flip cap* 100 ml bottle	20 bottles

\* flip cap: Infusion bottles with flip-off caps



Contact us for the total list of available products.



## QUALITY CONTROL STRAINS

EZ-Accu Shot is perfect for performing Growth Promotion Testing with ease! EZ Accu Shot™ Select Kit (item no. MIC.8172) includes one lyophilized microorganism pel-let, packaged in individual vials, for each strain, as well as individual vials of Hydration Fluid.

Compendial strains included are :

- Aspergillus brasiliensis derived from ATCC® 16404™
- Bacillus spizizenii derived from ATCC® 6633™
- Candida albicans derived from ATCC® 10231™
- Escherichia coli derived from ATCC® 8739™
- Pseudomonas paraeruginosa derived from ATCC® 9027™
- Staphylococcus aureus subsp. aureus derived from ATCC® 6538™



Contact us for the total list of available products.

## LAB EQUIPMENT THAT FIT YOUR NEEDS



Labconsult offers a broad range of laboratory equipment including installation IQOQ, testing and validation services.

## BIOLOGICAL SAFETY CABINET CLASS II FOR CYTOTOXICS



**Certified Safety: EN 12469.** The **BiOptima 4 & 6** and **Cyto 4 & Cyto 6** cabinets are independently tested and certified by TÜV Nord, the main certification body in Eu-rope, to guarantee conformity to standard EN 12469 for Class II biological safety cabinets (30% exhaust, 70% recirculation unit). **BiOptima Cyto** is designed for high risk microbiological and high toxic applications, such as the production of cytotoxic medicines, as specified by the DIN12980 Standard. Different sizes available, please enquire.



## I SKAN PURE<sup>2</sup> ISOLATORS

# skan

- **Model sizes:** 2-glove ports or 4-glove ports, with one (L/R) or two (L&R) optional airlocks
- **Operating modes:** Positive or Negative pressure operating modes depending on the application
- **Equipped with** the safest & most efficient fully automated **H<sub>2</sub>O<sub>2</sub> decontamination System SKANFog®** with integrated SKAN Nanox Catalyst system omitting the absolute need for an HVAC connection.
- **Compliance with** all cleanroom requirements (cGMP class A/ISO class 5 in accordance with ISO 14644), FDA 21 CFR Part 11 compliant through Siemens controller P7-1500 with 9" color touch screen control panel.
- **Fields of application:** (Hospital) Pharmaceutical manufacturing, Sterility Testing, Cell & Gene, ...
- **Ready for integration** with the **Sterility Testing Pump Sterisart® Universal Gen4** from **Sartorius**.



## SARTORIUS



## I MEMMERT INCUBATORS

# memmert

- temperature range up to +80 °C
- 8 model sizes (32 to 749 litres volume)
- 2 model variants: SingleDISPLAY & TwinDISPLAY
- natural convection or forced air circulation N/F
- double doors (interior glass, exterior stainless steel) for a clear view without a drop in temperature
- activation of sterilisation routine via ControlCOCKPIT (TwinDISPLAY)



**Contact us for the total list of available products.**



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