Preparation, Separation,

Filtration & Monitoring Products

unmatched comfort

in microbial testing with the Milliflex Oasis®system









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product presentation







TOP FEATURES

- Milliflex Protact®
- Milliflex Azure®

- Milliflex Trace®
- Milliflex Microlite®
- Milliflex Rack & Stack®

Milliflex Oasis® key features

Together with our customers we have developed a myriad of innovative features that will optimize your microbial testing workflow. Discover how each of them ease your daily work.









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TOP FEATURES

- Milliflex Protact[®]
- Milliflex Azure®

- Milliflex Trace®
- Milliflex Microlite®
- Milliflex Rack & Stack®



Reliability of microbial analysis is challenging for two main reasons: secondary contamination can produce false-positive results, and improper contact between the filter and the culture media can lead to false negative results. The Milliflex Protact® sum of features is designed to protect your samples from extrinsic microbial contamination and optimize your membrane-to-media contact for the most reliable results.





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TOP FEATURES

- Milliflex Protact®
- Milliflex Azure®

- Milliflex Trace[®]
- Milliflex Microlite®
- Milliflex Rack & Stack®

Milliflex Azure® feature

The Milliflex Azure® feature is a collection of features that allows the analyst to see that the accurate volume of sample is filtered as it should be.

The Milliflex Oasis® funnel material is crystal clear making it easy to visualize while the sample is poured, thanks to the colored contrast font on the pump, and the design of the funnel and its hydrophobic material ensures that no residual liquid remains unfiltered.







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TOP FEATURES

- Milliflex Protact®
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- Milliflex Rack & Stack®

Milliflex Trace[®] feature

The Milliflex Trace® feature offers complete traceability and comprises detachable labels, 2D codes that can be scanned for direct access to documentation, and unique identification for each funnel and each media plate. Traceability from A to Z: identification and 2D codes on primary packaging, secondary packaging and on each single unit, along with color coding to avoid mistakes. All-in-all, data integrity is brought to a higher level.





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TOP FEATURES

- Milliflex Protact[®]
- Milliflex Azure®

- Milliflex Trace®
- Milliflex Microlite®
- Milliflex Rack & Stack®

Milliflex Microlite® feature

The Milliflex Microlite® feature makes the hardware intuitive for both daily use and maintenance. It is composed of quick connections for both the power and the drain tubing, one button to both start and stop the pump, a small footprint, low weight, and many other ergonomic features that make the workflow so comfortable.





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TOP FEATURES

- Milliflex Protact®
- Milliflex Azure®

- Milliflex Trace®
- Milliflex Microlite®
- Milliflex Rack & Stack®



The Milliflex Rack & Stack® innovation will streamline your workflow: funnel trays can be stacked offering more space in the working area. Plates can be stacked and locked on the same trays for safe transportation and incubation.







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key benefits

Comfort on every level

Productivity

Regulatory Compliance

Result Reliability

When your day-to-day tasks are under control, your mind is free for other activities. We have taken the time to closely observe your complete workflow to identify improvements to simplify and secure your microbial testing process. Enjoy the comfort that Milliflex Oasis® system brings to your lab.





Application

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key benefits

- Productivity
- Regulatory Compliance

• Result Reliability

The comfort of productivity

- Fast hardware set-up and 50% faster filtration time (vs. previous Milliflex® product)
- Hardware scalability: attach up to three pumps and filter 6 samples with a single push of a button
- Fastest possible touch-free membrane transfer
- Barcode and detachable labels replace manual, time-consuming record keeping
- Reduced decontamination time and maintenance, no need for autoclaving







Application

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key benefits

- Productivity
- Result Reliability
- Regulatory Compliance

The comfort of reliability

Unique features help to prevent secondary contamination of samples:

- Operator independent system
- Touch-free membrane transfer
- Perfect contact between the membrane and the media plate

- A check valve situated in the pump head prevents backflow contamination
- Color-coded funnels, media plates and labels aid identification and minimize the risk of errors







key benefits

- Productivity
- Regulatory Compliance
- Result Reliability



The comfort of regulatory compliance

Pharmaceutical regulatory compliance is a key topic for QC labs to ensure accurate results and safe products for patients. Membrane filtration using the Milliflex Oasis® system reduces secondary contamination risks and maintains compliance with USP, EP and JP recommendations.

• Labels with 2D Code on the packaging, on each funnel and each media plate: lot number and

expiration date can be checked and recorded as mentioned in USP<117> microbiological best laboratory practices

- Detachable label on primary/secondary package for easy transfer to log books.
- Unique identification for each funnel and each media plate type (R2A-TSA-SDA).





pata sheet

Milliflex Oasis® system Data Sheet



Not only comfortable to use, the Milliflex Oasis® system is relaxing for your mind:

96 new features take care of all that matters for lab productivity, reliability of results and regulatory compliance. We offer you a total solution for your workflow with secured steps and high throughput capabilities.

Three components (and services) combine to give you a complete solution:

- All-in-one filtration equipment
- Ready-to-use sterilized filtration units
- Pharmacopeia compliant culture media





photo gallery

Funnel

Pump

Media

System

Crystal clear funnel material



Integrated membrane support



Convex membrane shape for perfect contact with the agar

Stackable funnel trays





Effortless funnel separation by pinching





photo gallery

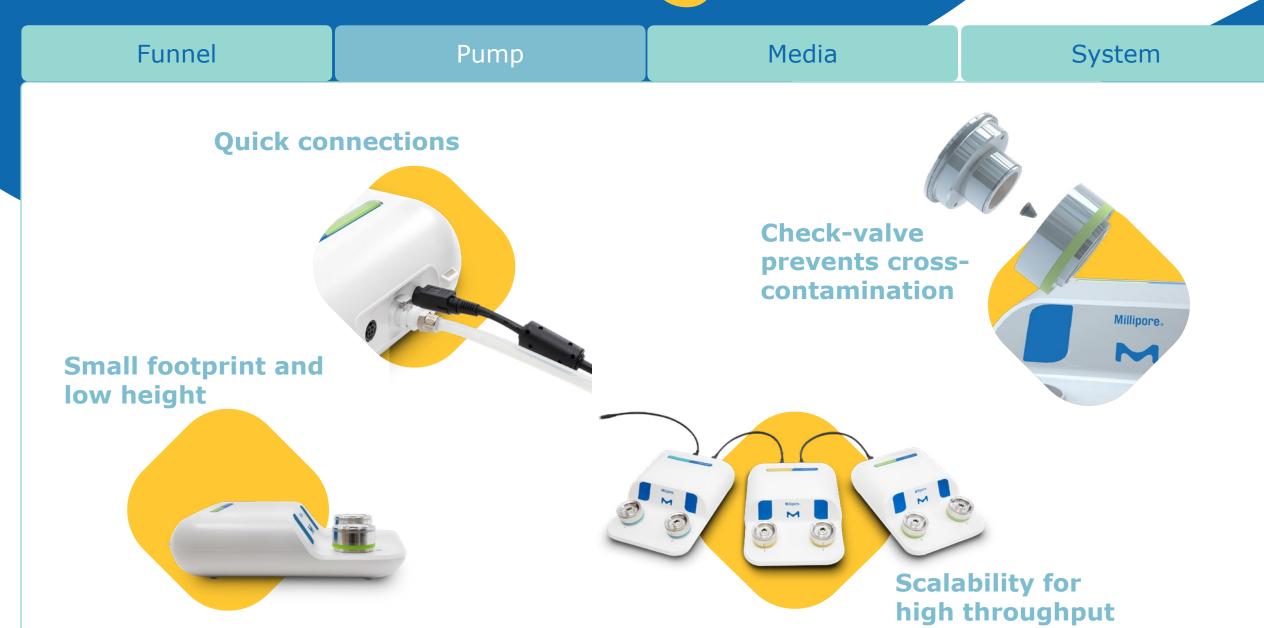






photo gallery

Funnel Pump Media System





Lockable assembly for safe transportation



Tight lid closure for longer storage





X

photo gallery

Funnel Pump Media System







Color-coding on boxes, funnels and media plates





Pharmaceutical industry

Membrane Filtration Method

Membrane type

Regulations

During the manufacturing of a drug, the quantity of microorganisms must be monitored according to regulations, methods, or country directives that may apply. The objective is to ensure that the water, raw materials, in-process samples and finish-products meet the required specifications

to demonstrate that each process is in a state of microbial control. Bioburden testing or microbial testing is routinely performed, usually via membrane filtration, which is considered the standard method for any sample that is filterable.





Pharmaceutical industry

Membrane Filtration Method

Membrane type

Regulations

Membrane filtration is the method of choice endorsed by regulatory bodies to produce analytical results of known quality. It allows for the retention and recovery of microorganisms on culture media which generates a quantitative result. The liquid sample is filtered and then the microorganisms are retained on the membrane. This membrane is then

transferred onto a media selected for the application and incubated at a specific temperature for a period of time depending on the type of microorganism. The microbes will begin to replicate under incubation to form colony forming units (CFU). Each colony is then counted as one microorganism.





Pharmaceutical industry

Membrane Filtration Method

Membrane type

Regulations

Membrane filters with a 0.45 μ m pore size have long been recognized as the standard for optimum growth of microorganisms. Among all the available membrane pore sizes for microorganism enumeration, membranes of 0.45 μ m pore size are the best choice for microbial analysis considering the flow rate, throughput, and microbial recovery. 0.45 μ m mixed cellulose ester (MCE)

membrane filters are one of the most widely used membranes for bioburden applications. For samples with anti-microbial activity (i.e., antibiotics) or solvents, polyvinylidene difluoride (PVDF) membranes are often used because of their very low protein binding property. Durapore® membranes minimize sample interaction and maximize recovery of microorganisms for these bioburden applications.





Pharmaceutical industry

Membrane Filtration Method

Membrane type

Regulations

The unique features of Milliflex Oasis® filtration units allow users to follow the regulations that apply:

USP <1227> Validation of Microbial recovery from Pharmacopeial Articles (PVDF membranes are cited to avoid residual antimicrobial effects).

USP <61> & EP 2.6.12 & JP 4.05 part 1 (Fully Harmonized) Microbiological examination of non-sterile products: microbial enumeration

tests (Milliflex Oasis® filtration units are designed to reduce contamination risk to the minimum).

ISO 8199 Water quality — General guidance on the enumeration of microorganisms by culture (filtration and transfer of the membrane onto the media are designed to optimize user's workflow).





Milliflex Oasis® System Services

To request a quote for a method development, IQ/OQ service, PQ consultancy, preventive maintenance, service plan or training, please contact your, local sales representative.





Preparation, Separation, Filtration & Monitoring Products

Method development

Consider it done

When a microbial test method (SOP) is to be set up for a new product, or improved for a product that demonstrates antimicrobial effects and/or filtration issues, our application scientists can develop a method that is compliant with international regulations (pharmacopoeias).

Whether you need help with a new pharmaceutical test method, or optimizing an existing method, we are ready to lend a hand.





validation protocols

Ready-to-use validation protocols

Validation workflow

Validation Protocols



Leave it to us

cGMPs and cGLPs require equipment and test methods to be validated before routine use. Our ready-to-use validation protocols for pharmaceutical testing are based on our internal product qualification test methods. These extensive protocols will enable the QC/QA lab to quickly initiate your Validation Master Plan and perform IQ, OQ and PQ (suitability of the test methodology) with ease.



validation protocols

Ready-to-use validation protocols

Validation workflow

Validation Master plan

• Defined structure, responsibilities for qualification





operational Qualification (oQ)

Verification of product's functionality (hardware, software, devices)





Installation Qualification

- Verification identification of the equipment
- Verification of product's utilities and operating environmental requirements
- Equipment and personnel preparation

Final report

 Summarizes all testing performed for final approval of validation



Performance Qualification (PQ)

• Test method suitability verification (microbiology validation procedures)



validation services

We have experienced and trained validation engineers who are skilled to assist in validation protocol implementation within the QC microbiology laboratory, so the QC/QA departments do not have to allocate resources. A basic technical training on your installed equipment is also provided during the validation engineer's visit. Rely on our expertise in various situations such as:

- New lab equipment
- New product or reformulated product to be tested
- Compliance with updated regulations: EP, USP, JP, etc.

After the IQ/OQ has been completed we can support with PQ consultancy, advanced operator training and requalification services on a yearly basis.





Maintenance & service plans

Annual preventive maintenance

Breakdown and spare parts

Service plans

Efficient operation

Preventive maintenance and system verification enables efficient operation of critical testing equipment. Every Milliflex Oasis® pump should be serviced regularly to ensure its performance remains compliant with the specifications, as per GLP and GMP.

We recommend checking and calibrating the pump on an annual basis. Upon completion of the service, we will provide you with a report defining the service performed on your pump as well as our recommendations.





Maintenance & service plans

Breakdown and spare parts

Service plans

Reduce the risk

Annual preventive

maintenance

Annual preventive maintenance will reduce the risk of breakdown and ensure that your Milliflex Oasis® pump works within system specifications. However, in case a breakdown does occur on your pump, our service team will repair it as diligently as possible at your site or in our local service center. Depending on your service plan level spare parts and labor are covered during the service plan validity period (Total plans only).







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maintenance & service plans

Annual preventive maintenance

Breakdown and spare parts

Service plans

You have the choice between 3 coverage levels

	Service Essential™	Service Advanced™	Service Total™
Preventive maintenance	Yes (1/ year)	Yes (1/ year)	Yes (1/ year)
Maintenance kit (quoted separately)	Yes	Yes	Yes
Number floating repair (labor and shipment/ travel)	No	Yes (1/ year)	Yes (unlimeted)
Spare parts	No	No	Yes
Shipment Basic travel zone*	Yes	Yes	Yes
Options	To be ordered separately		
Second preventive maintenance	Yes	Yes	Yes

^{*} Return shipment only. Additional travel may be quoted separately.



Training



Milliflex® School and advanced operator training

We offer 2 courses. Both provide an in-depth review of the regulatory requirements of pharmaceutical testing, its validation and practical implementation. The advanced operator training will offer an additional individual practical session with final examination.

Why take chances?

Be confident of your results with our comprehensive pharmaceutical testing solutions. To discuss a specific pharmaceutical testing application, please contact your local sales representative.

Your benefits

- Take preventive actions to avoid false positive or false negative test results
- Develop and optimize pharmaceutical testing procedures
- Understand and identify root causes for common handling issues



sustainability

Responsible Waste Management with Milliflex Oasis® consumables



We are committed to sustainability, and we recognize that every product we make also has an environmental impact. Therefore, we investigate new and alternative waste management solutions for our products, including our Milliflex Oasis® devices. Our fact sheet gives you suggestions to consider on how you can dispose of Milliflex Oasis® consumables responsibly after use, considering different levels of access to appropriate waste management practices.









Filtration units Culture media Hardware, accessories, spare parts

Filtration units	Qty/ pack	Article number
Milliflex Oasis® 100 mL funnel, 0.45 μm white gridded, mixed cellulose esters (MCE) membrane	24	MMHAWG124
Milliflex Oasis® 250 mL funnel, 0.45 μm white gridded, mixed cellulose esters (MCE) membrane	24	MMHAWG224
Milliflex Oasis® 100 mL funnel, 0.45 μm black gridded, mixed cellulose esters (MCE) membrane	24	MMHABG124
Milliflex Oasis® 100 mL funnel, 0.22 μm white gridded, mixed cellulose esters (MCE) membrane	24	MMGSWG124
Milliflex Oasis® 100 mL funnel, 0.45 μm white plain PVDF Durapore® membrane	24	MMHVWP124
Milliflex Oasis® 250 mL funnel, 0.45 μm white plain, PVDF Durapor® membrane	24	MMHVWP224
Milliflex Oasis® rapid 100 mL funnel, 0.45 µm white plain, PVDF Durapore® membrane	24	MMHVMFX24
Milliflex Oasis® funnel without membrane, growth promotion accessory	24	MMRECVERY

* Return shipment only. Additional travel may be quoted separately.



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Filtration units	Culture media	Hardware, accessories, spare parts		are parts
Culture media			Qty/ pack	Article number
Milliflex Oasis® R2A low nutrient media p	lates		48	MMSMCRA48
Milliflex Oasis® tryptic soy media plates f	or detection of aerobic and anaerobic flor	та	48	MMSMCTS48
Milliflex Oasis® sabouraud dextrose med	a plates for detection of yeast & molds		48	MMSMCSD48
Milliflex® cassette sabouraud dextrose ag	gar (w/Chloramphenicol)		48	MXSMCSP48
Milliflex® cassette m-Endo agar for the detection of coliforms		48	MXSMEND48	
Milliflex® cassette PCA agar for the detection of bacteria in water		48	MXSMPCA48	
Milliflex® cassette cetrimide agar with naladixic acid for detection of <i>P. aeruginosa</i>		48	MXSMCET48	
Milliflex® cassette TSA and lecithin agar	for the detection of heterotrophic microor	ganisms	48	MXSMTLP48
Milliflex® cassette HPC agar media, for detection of stressed heterotrophic plate count bacteria		48	MXSMHPC48	
Milliflex® cassette KF strep agar for the detection of fecal streptococci		48	MXSMKFS48	
Milliflex® cassette PIA agar for the detection and recovery of <i>P. aeruginosa</i>		48	MXSMPIA48	
Mac Conkey Milliflex® agar for detection	of lactose fermenting bacteria and colifor	ms	24	MXSMCMC24
Milliflex® empty cassette for agar media			120	MXSMC0120
Milliflex® empty cassette for liquid media			120	MXLMC0120

^{*} Return shipment only. Additional travel may be quoted separately.







Filtration units Cul	Tire media	Hardware, accessories, spare parts and services
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Hardware, accessories, spare parts and services	Qty/ pack	Article number
Milliflex Oasis® filtration pump, one system with two filtration heads and no power supply	1	MMSYSTMM1
Milliflex Oasis® filtration pump without filtration head and no power supply	1	MMSYSTVAC
Milliflex Oasis® power supply for one to three filtration pumps - Australia	1	MMPWRSPAU
Milliflex Oasis® power supply for one to three filtration pumps - Brazil	1	MMPWRSPBR
Milliflex Oasis® power supply for one to three filtration pumps - China	1	MMPWRSPCN
Milliflex Oasis® power supply for one to three filtration pumps - Denmark	1	MMPWRSPDK
Milliflex Oasis® power supply for one to three filtration pumps - Europe	1	MMPWRSPEU
Milliflex Oasis® power supply for one to three filtration pumps - India	1	MMPWRSPIN
Milliflex Oasis® power supply for one to three filtration pumps - Japan	1	MMPWRSPJP
Milliflex Oasis® power supply for one to three filtration pumps - Switzerland	1	MMPWRSPSZ
Milliflex Oasis® power supply for one to three filtration pumps - United Kingdom	1	MMPWRSPUK
Milliflex Oasis® power supply for one to three filtration pumps - United States	1	MMPWRSPUS
Milliflex Oasis® power supply for one to three filtration pumps - South Africa	1	MMPWRSPZA
Milliflex Oasis® filtration head	1	MMHEADMM1

Part 1

Part 2

Part 3

* Return shipment only. Additional travel may be quoted separately.







Filtration units	Culture media	Hardware, accessories, spare parts and services		
Hardware, accessories, spare parts and services			Qty/ pack	Article number
Milliflex Oasis® filtration head gaskets re	placement kit, including gaskets removal	tool	5	MMGASKTMM
Milliflex Oasis® filtration head cover set			1	MMHEADCV1
Milliflex Oasis® drain tubing			1	MMDRNTUBE
Milliflex Oasis® internal flow sanitization	kit, including one vacuum gauge		1	MMSANKIT1
Milliflex Oasis® internal flow sanitization gasket kit			5	MMGASKTSK
Milliflex Oasis® consumables for internal flow sanitization kit			24	MMSANSYFU
Milliflex Oasis® vacuum gauge for pump performance testing			1	MMGAUGEMM
Milliflex Oasis® electrical cable for connecting two pumps			1	MMCABLEMM
Milliflex Oasis® T connectors for tubings for connecting two pumps			3	MMTCNNECT
Milliflex Oasis® guides for electrical cable and tubing		20	MMTUGUIDE	
Milliflex Oasis® membrane support removal tool			1	MMSUPREMV
Stickers and filtration head rings for customizing the Milliflex Oasis® pump			4	MMCUSTKIT
Milliflex® Quantum membrane transfer tool for Milliflex Oasis® system			1	MMHEADQU1
Milliflex® Quantum membrane transfer to	ool for Milliflex Oasis® gaskets replacemer	nt kit	5	MMGASKTQU
Doub 1 Doub 2 Doub 2				

* Return ship ment only. Additional travel may be quoted separately.





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Part 2

Filtration units	Culture media	Hardware, access and services	Hardware, accessories, spare parts and services		
Hardware, accessories, spare parts and	services		Qty/ pack	Article number	
Customer validation protocol format A4			1	MM2PA4VP1	
Customer validation protocol format letter			1	MM2PLTVP1	
Customer validation protocol format letter			1	MM2PLTVP1	
Part 1 Part 2 Part 3			OF	RDER NOW	







Contact

For further information on the Milliflex Oasis® system, please contact your local sales representative or visit our website MerckMillipore.com/Offices.

CONTACT US



MerckMillipore.com/Milliflex-Oasis



Merck KGaA Frankfurter Straße 250, 64271 Darmstadt, Germany

To place an order or receive technical assistance in Europe, please call Customer Service:

France: 0825 045 645 Germany: 069 86798021 Italy: 848 845 645,

Spain: 901 516 645 Option 1 Switzerland: 0848 645 645 United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Buy the right culture medium for you: **MerckMillipore.com/Biomonitoring**

For Technical Service, please visit: MerckMillipore.com/TechService

For other countries across Europe and the world, please visit: **MerckMillipore.com/offices**

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MK_BR1617EN 03/2019



