# DELABIE

Anti-Legionella and all-germ point-of-use filters





- Tap & wall-mounted shower filters
- Shower head filters
- Spout filters

# DELABIE

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Certification ISO 9001: 2015 quality management systems

# ACS

Certificate of Sanitary Conformity. All DELABIE products conform to the CPDW\* directive modified 29/05/1997, and the French Ministry of Health circular

DGS/SD7A2002 no. 571 dated 25/11/2002. \* Construction Products in Contact with Drinking Water (European Commission).



# Anti-Legionella and all-germ point-of-use filters





**BIOFIL** filter for mixers and taps



BIOFIL spout filter for BIOCLIP mixers and taps



BIOFIL shower head filter



**BIOFIL** filter for wall-mounted showers

# **CONTROLLING WATERBORNE HEALTH RISKS**

Water, essential for hygiene, can also be a source of infection if its quality is not controlled. The proliferation of bacteria (Legionella spp., Pseudomonas aeruginosa, etc.) in the water supply or in mixers and taps may cause serious infections, especially for vulnerable people.

Water systems in all buildings open to the public should be monitored for Legionella (e.g. hotels and holiday accommodation, campsites, detention centres, etc.) and not just healthcare facilities. The HSE Approved Code of Practice and Guidance (ACOP) document L8 states that duty holders should: identify and assess sources of risk of exposure to Legionella; put in place precautions to prevent or control that risk; and monitor these measures to ensure that they remain effective. This applies in all circumstances where the Health and Safety at Work Act 1974 applies.

The prevention of health risks associated with pathogenic bacteria in water systems should be a constant concern for public buildings, and in particular healthcare facilities (see the current guidance opposite).

The BIOFIL range of point-of-use filters provides a preventative or curative solution to secure the water quality at the point-of-use and protect the health of the user.

# **CURRENT GUIDANCE**

HSE guidance HSG274 Part 2 (2014) and DHSC Health Technical Memorandum (HTM) 04-01 Part B (2016) provide guidance for the control of Legionella in hot and cold water systems and on providing safe water in healthcare premises respectively

Point-of-use filters prevent the discharge of planktonic Legionella from the tap and shower outlets and may be used to provide water free of *P. aeruginosa*. They should be used primarily as a temporary measure until a permanent, safe engineering solution is developed, although long-term use of such filters may be needed in some healthcare situations. They may also be considered where a high level of disinfection of water systems may dislodge biofilm. Point-of-use micro-filters with a 0.2µm membrane constitute a means for removing Legionella and Pseudomonas aeruginosa in water drawn off from the system.

#### HTM 04-01 Part C (2016) provides advice on managing Pseudomonas aeruginosa in augmented care units

For direct contact with augmented care patients, water of a known satisfactory quality should be used, that is, either: water where testing has shown absence of P. aeruginosa; or water supplied through a POU filter; or sterile water (for example, for skin contact for babies in neonatal intensive care units).

#### HSG274 Part 2 states that monitoring for Legionella should be carried out:

- when water is treated with biocides and when distribution temperatures are reduced from HSE guidelines.
- where water treatment regime control levels are not being consistently achieved.
- where there is a high-risk of contamination e.g. hospitals and care homes.
- where an outbreak of legionellosis has been identified.

When a sample identifies a Legionella count above 100 CFU/Litre (Colony Forming Unit) an immediate review of the control measures and risk assessment should be carried out to identify any remedial action required. Disinfection of the system should also be considered.

Point-of-use micro-filters are a means to restore the bacteriological quality of water at the point-of-use (anti-Legionella and all-germ tap filters and shower heads, etc.).

# ANTI-LEGIONELLA AND ALL-GERM RANGE OF BIOFIL FILTERS

#### DELABIE offers a collection of BIOFIL water filtering devices: tap and wall-mounted shower filters, shower head filters and spout filters

BIOFIL filters are designed to deliver bacteriologically controlled water at the point-of-use. These devices retain bacteria, including waterborne opportunistic pathogenic micro-organisms such as *Legionella spp., Legionella pneumophila, Pseudomonas aeruginosa,* non-tuberculous Mycobacteria and other micro-organisms, thanks to a hollow fibre micro-filtration membrane with a porosity of 0.1µm nominal-rated. This micro-filtration technology guarantees a bacteriological quality superior to that of the drinking water system without changing its chemical composition.

# BIOFIL filters are designed to secure water delivery at the point-of-use.

They are recommended for managing and preventing so-called healthcare associated infections (HAIs).

# AREAS OF USE

# Anti-Legionella and all-germ filters

BIOFIL 2, 3 and 4-month point-of-use filters provide a physical barrier to reduce the risk of infection associated with waterborne micro-organisms. The micro-filtration membrane provides protection for immunosuppressed and vulnerable people.

### Filters are necessary for the care of

immunosuppressed patients in high risk areas such as bone marrow and organ transplant units, oncology, intensive care, neonatal wards and any other area providing care for this type of patient. They also provide protection against the risk of legionella and ensure compliance with regulations for users of public buildings.

# **NO CHEMICAL PRODUCTS**

No chemical products are used during the manufacture of our filters.

# TOTAL CONTROL OF THE MANUFACTURING PROCESS

### 100% quality controlled

The fibre quality and porosity of the finished product are continuously monitored during the manufacturing process for 100% of the fibres.

# COMPONENT DISPOSAL STRATEGY

BIOFIL filters are classified as household waste. The outer packaging is made from recycled cardboard which is also fully recyclable.

# HOLLOW FIBRE, AN INNOVATIVE, TECHNICAL SOLUTION

## Hollow fibre micro-filtration

There are two main types of membrane used in point-of-use micro-filtration devices: flat membrane or tubular membrane.

DELABIE chose to use hollow fibre tubular membrane filtration technology.

# THE PRINCIPLE OF HOLLOW- FIBRE FILTRATION

## Hollow fibre filter

The BIOFIL filter is made up of a collection of polyethylene hollow fibres grouped together into a unit. The fibres are extremely fine and flexible, with an outer diameter of 0.6mm and a thickness of several tens of microns.

The fibres are hollow and shaped like a straw (tubular).

## Microporous structure

The hollow fibre membranes have multiple pores which vary in size from 0.01 - 0.1 micron. Each membrane consists of several surfaces with microporous structures (micro slits).

#### Bacteria and any particles in suspension that are larger than 0.1 micron are trapped by these structures and are retained permanently on the external surface of the membrane.

# External/Internal frontal filtration

DELABIE uses a frontal filtration system. The water requiring treatment flows at right angles to the filter surface and passes through the membrane due to the pressure difference on either side of the membrane.

# The water flows from the external to the internal surface of the fibre.

Bacteria and other microparticles that cannot pass through the gaps in the membrane structure are retained on the outer surface and therefore do not penetrate the membrane.

# Filtration area/storage of bacteria

The filter's large hollow fibre filtration surface area makes it possible to filter a larger volume of water.

Consequently the storage capacity for bacteria and impurities trapped inside the filter is much greater.



Hollow fibre membrane



Microporous structure



External/internal frontal filtration



Large filtration area Optimised bacteria storage



Bacteriologically controlled water



Section of the BIOFIL tap filter



Maximum lifespan



Tilted to optimise the position of the tap filter



CE marked class I Medical Devices for non-sterile filters CE marked class Is Medical Devices for sterile filters

# **BACTERIAL CHALLENGE**

# BIOFIL filters are approved using the ASTM F838\* method.

This test confirms the effective bacterial retention power of the filters used for the decontamination of liquids.

The microbiological challenges carried out on BIOFIL filters in laboratories using the species *Brevundimonas diminuta, Legionella pneumophila and Pseudomonas aeruginosa* demonstrate

a retention efficiency of  $\log^7$  for all waterborne micro-organisms which are larger than the filter pores which have a nominal porosity rating of 0.1µm and absolute porosity rating of 0.2µm.

When subjected to this test, all BIOFIL filters delivered an effluent free from bacteria, so they have a sterilising grade of 0.1 micron nominal-rated.

\* Standard Test Method for Determining Retention of Membrane Filters Utilized for Liquid Filtration.

# LIFESPAN

BIOFIL anti-Legionella and all-germ filters can be used for up to 4 months after initial installation (depending on the model installed). After the time period marked on the filter (2, 3 or 4 months), DELABIE recommends changing the filter to avoid any risk of retro-contamination from the bacteria concentrated in the filter especially in at-risk areas.

**Note:** The amount of impurities in the water will vary between water systems. Filters will, therefore, become clogged at different rates. If the filter becomes clogged prematurely, it is necessary to change it. We recommend pre-filtration upstream to filter out suspended solids and/or colloids, etc.

Bacterial proliferation is significantly reduced in an installation where the water is pre-filtered, and the lifespan of all equipment is greatly increased.

# RESISTANT TO DIFFERENT WATER SYSTEM TREATMENTS

BIOFIL filters will withstand thermal and chemical shocks. During chemical or thermal shocks, impurities become trapped in the filter and reduce its lifespan. DELABIE, therefore, recommends changing the filter after any treatment.

#### Resistance to thermal shocks:

Temperatures of 70°C for a cumulative period of 30 minutes during its lifetime.

#### Resistance to chemical shocks:

Chlorine levels for 2-month filters: 2 hours at 100ppm; 3-month filters: 3 hours at 100ppm; and 4-month filters: 4 hours at 100ppm.

# **OPTIMISED TRACEABILITY**

To control the health risks associated with water, the whole process from the manufacture of the medical device components to the use of the finished product must be completely traceable.

#### Individual packet label

All BIOFIL filters have a unique batch number which can be easily traced back through the production process.



#### Double labelling on the filter

All filters are supplied with 2 waterproof labels which identify the product and ensure traceability when the filter is changed.

One is positioned on the product, the other can be removed and transferred to the record log, ensuring traceability.



# COMPLIANCE

#### **CE marked class I Medical Devices**

BIOFIL non-sterile filters comply with the European Regulation EU 2017/745 and benefit from the CE Mark (2022).

#### **CE marked class Is Medical Devices**

BIOFIL sterile filters comply with the European Regulation EU 2017/745 and benefit from the CE mark (2022).

# Sterilisation complies with European standard EN ISO 11137

After manufacture, BIOFIL sterile filters are sterilised using gamma rays. Each box has a visual marker showing that the filters have been sterilised. After sterilisation, BIOFIL filters have a shelf life of 3 years. The product expiry date is marked on the label.

#### Certificate of sanitary compliance

All BIOFIL filters conform to the CPDW directive and the Order of 29 May 1997, as amended, and the French Ministry of Health Circular DGS/SD7A2002 no. 571 of 25 November 2002.

#### WRAS

Our BIOFIL filters are WRAS approved. WRAS Approval demonstrates that a product complies with the Water Supply (Water Fittings) Regulations and Scottish Water Byelaws. The WRAS approval standard is accepted as a **quality benchmark** by water suppliers who enforce the Water Regulations and Byelaws.



#### **EASY TO INSTALL** - Tap and wall-mounted shower filters: simply connect to the outlet requiring treatment, no tools required, using push-fit connectors - Shower heads: can be screwed

onto any standard shower hose

**PROTECTIVE SKIRT** Filter outlet protected from any contamination by hand

#### **TOTAL PROTECTION**

Bacteriologically controlled water: hollow fibre membrane with a water filtration threshold of 0.1µm nominalrated and 0.2µm absolute-rated

- Very large filtration area:
- higher volume of filtered water than
- Completely effective and reliable
- with drinking water of any quality
- clogging: large capacity to store bacteria inside the filter
- Filter lifespan up to 4 months

#### SPOUT FILTER

- No additional space required: drop height maintained - Removes the spout as a potential contaminant



: Water flow through the filter

Mechanical basin mixer 2565T1 - BIOFIL 2-month anti-Legionella and all-germ tap filter 30250 - Push-fit connector M24 × 100 820124N

# **BIOFIL tap and wall-mounted shower filter**

Anti-Legionella and all-germ filter

• Hydrophilic polyethylene hollow fibres.

12,000L for 4 months.

• Available in two versions:

Ø 56

20250/30250 20251/30251



• Single use filter for taps and wall-mounted showers, sterilising grade 0.1 µm nominal-rated.

• Maximum lifespan: 2, 3 or 4 months after installation depending on the model installed.

• Volume of water filtered per duration of use: 6,000L for 2 months; 9,000L for 3 months;

• Filtration flow rate: 5.5 lpm\* at 3 bar for 2-month versions; 7.6 lpm\* at 3 bar for 3 and 4-month

versions (filter only, excludes any flow rate restrictor/regulator in the shower or mixer).

• Careful management of retro-contamination: protective skirt and filter position

• Space saving, suitable for mixers and taps with a low drop height.

• Compatible with and resistant to chemical and thermal shocks. • CE marked class | Medical Device for non-sterile versions.

• CE marked class Is Medical Device for sterile versions.

- sterile filters, individually wrapped in sterile packaging;

Tilted connector to optimise

- non-sterile filters, individually wrapped in non-sterile packaging.

• Maximum upstream pressure at point-of-use: 5 bar.

is optimised thanks to a tilted connector.

\* Average flow rate during the product lifespan.



WRAS

# **Related products**



#### **Push-fit connector** · Simple to connect to the

- point-of-use requiring treatment, no tools required.
- Standard or vandal-resistant versions available.



821123



22x100



820123





Vandal-resistant version: Tamper-proof connector

820126N

prevents vandalism and unauthorised removal of filter.

Push-fit connector for mixer/tap filters

i ush ni connector for mixer tup miters	
M24×100	820124N
M24 $ imes$ 100, vandal-resistant version	821124
F22×100	820122N
F22 × 100, vandal-resistant version	821122
M1⁄2"	820123
M½", vandal-resistant version	821123
M16.5×100	820126N
Push-fit connector for wall-mounted shower fi	Iters
M24 × 125	820125
M24 $ imes$ 125, vandal-resistant version	821125
These connectors are suitable for use with the new shown opposite.	range of filters

Filter position can be adjusted to prevent the water flowing directly onto the waste. Reduces the risk of retro-contamination.

filter position:



011		
	50	66
Ø 56		
20350/3039 20351/3039		

shower spray

laminar flow

20450/30450 20451/30451

#### 1 BIOFIL tap and wall-mounted shower filter\*

2-month lifespan	
Sterile, shower spray	20250
Sterile, laminar flow	20251
Non-sterile, shower spray	30250
Non-sterile, laminar flow	30251
3-month lifespan	
Sterile, shower spray	20350
Sterile, laminar flow	20351
Non-sterile, shower spray	30350
Non-sterile, laminar flow	30351
4-month lifespan	
Sterile, shower spray	20450
Sterile, laminar flow	20451
Non-sterile, shower spray	30450
Non-sterile, laminar flow	30451

\* Reference is for a single unit. Can only be ordered in multiples of 10 (packaged in boxes of 10).

# **BIOFIL shower head filter**

Anti-Legionella and all-germ filter



- Single use shower head filter, sterilising grade 0.1µm nominal-rated.
- Quick to install: screws on to all standard shower hoses.
- Hydrophilic polyethylene hollow fibres.
- Maximum lifespan: 2, 3 or 4 months after installation depending on the model installed.
- Volume of water filtered per duration of use: 6,000L for 2 months; 9,000L for 3 months; 12,000L for 4 months.
- Filtration flow rate: 11.2 11.8 lpm\* at 3 bar depending on the model (filter only, excludes any flow rate restrictor/regulator in the shower).
- $\bullet\,$  Maximum upstream pressure at point-of-use: 5 bar.
- Compatible with and resistant to chemical and thermal shocks.
- CE marked class I Medical Device for non-sterile versions.
- CE marked class Is Medical Device for sterile versions.
- Available in two versions:
- sterile filters, individually wrapped in sterile packaging;

non-sterile filters, individually wrapped in non-sterile packaging.
Very light hand spray:

- 2-month version: empty filter: 105g; filter filled with water: 186g.
   3 & 4-month versions: empty filter: 133g; filled with water 253g.
- \* Average flow rate during the product lifespan.







20261/30261

20361/30361/20461/30461

1 BIOFIL shower head filter*	
2-month lifespan	
Sterile	20261
Non-sterile	30261
3-month lifespan	
Sterile	20361
Non-sterile	30361
4-month lifespan	
Sterile	20461
Non-sterile	30461
* Reference is for a single unit. Can only be ord	ered in multiples of 10 (packaged in

 Reference is for a single unit. Can only be ordered in multiples of 10 (packaged ir boxes of 10).



## **BIOFIL spout filter**

Anti-Legionella and all-germ filter



- Single use spout filter, sterilising grade 0.1µm nominal-rated.
- Can be installed instead of BIOCLIP spouts (does not require tools or the water to be shut off).
- Hydrophilic polyethylene hollow fibres.
- Maximum lifespan: **2** months after installation.
- Qualified water volume per duration of use: 6,000L.
- Filtration flow rate: 6 lpm\* at 3 bar (filter only, excludes any flow rate restrictor/regulator in the mixer).
- Maximum upstream pressure at point-of-use: 5 bar.
- Compatible with and resistant to chemical and thermal shocks.
- Available in two versions:
- sterile filters, individually wrapped in sterile packaging;
- non-sterile filters, individually wrapped in non-sterile packaging.
- \* Average flow rate during the product lifespan.



20040/30040

#### Ouick and easy to install: Pull the BIOFIL spout towards you to remove it.

2 Insert another spout filter in its place

1 BIOFIL spout filter*	
2-month lifespan	
Sterile	20040
Non-sterile	30040

### **Related products**



# BIOCLIP mixer

# with swivelling spout High, removable, swivelling

- spout H. 180mm, made from stainless steel L. 185mm. • Spout can be replaced
- by a BIOFIL filter spout (see opposite).
- Ø 35mm ceramic cartridge, standard or pressurebalancing.
- Flow rate limited to 5 lpm at 3 bar.
- Hygiene control lever L. 185mm requires no manual contact.



Mechanical mixer with BIOCLIP swivelling spout H. 180 L. 185	
Mixer with pressure-balancing	2870T1EP
Mixer with standard ceramic cartridge	2870T1

For more information, see our Healthcare catalogue, DOC 900UK.



#### TEMPOMATIC MIX electronic mixer with BIOCLIP spout

- Removable, swivelling spout made from stainless steel.
- Spout can be replaced by a BIOFIL filter spout
- (see opposite). • Shockproof infrared
- Presence detection sensor.
  Hygiene lever L. 100mm controls temperature.





TEMPOMATIC MIX mixer with swivelling spout	
Mains supply	
BIOCLIP, H. 160mm L. 183mm, 5 lpm	20870T1
BIOCLIP, H. 300mm L. 185mm, 9 lpm	20870T3

#### AVAILABLE CATALOGUES:

DOC 609UK: Water Controls for Public and Commercial Places

DOC 900UK: Water Controls for Healthcare Facilities and Retirement Homes

DOC 950UK: Accessibility and Independence - Hygienic Accessories for Public and Commercial Places

DOC 750UK: Stainless Steel Sanitary Ware

**DOC 200UK:** Water Controls for Professional Catering









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