



Manufacturing Forward

## **FILTRATION SOLUTIONS FOR PHARMACEUTICAL INDUSTRY**

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

  
**mikropor**

Manufacturing Forward





Mikropor began its journey in 1987 with a passion to create “Tomorrow’s Technology” and has become one of the leading manufacturers of atmospheric air filtration solutions and compressed air treatment systems for a variety of industries.

By closely following the latest developments in technology, Mikropor’s “Best in Class” products and solutions are appreciated by customers in more than 140 countries.

The company’s sustainable growth has been provided by its passion for innovation and commitment to quality, as well as its dedication to technology. Mikropor is environmentally conscious company that values people, while developing products that extend the needs and expectations of customers.

With this mission, Mikropor continues to become one of the most recognized brands in the world by expanding its global penetration in the field of technological filtration and contributes to a healthier planet.

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



## LEADER IN AIR FILTRATION SOLUTIONS

Choosing the right filter for a pharmaceutical application is extremely critical. From the AHU (Air Handling Unit) to the final output, the filtration system plays a crucial role in keeping pharmaceutical grade air free from airborne contaminants, bacteria, viruses and hazardous gases.

Mikropor offers a wide variety of solutions including high efficient EPA, HEPA & ULPA filters and leakage free hood and box variations. Mikropor guarantees the performance and impermeability (leakproof) by using the EN 1822 test standard. Each of the HEPA filters are individually scan tested before packaging. All EPA, HEPA & ULPA class filters are delivered with test certificates.

**Mikropor is a global leader in air filtration solutions for the pharmaceutical & life science industry and works closely with several of the largest pharma manufacturers worldwide.**





Indoor Air Quality plays a significant role in the protection of personal health. Healthcare facilities pay particular attention to reduced particle counts and the elimination of bacteria and airborne molecular contaminants. Mikropor provides a wide array of filter options to meet the critical needs of all areas of concern related to HVAC Systems in healthcare institutions.

## **Industries requiring pure, clean air;**

- Pharmaceutical Industry
- Biotechnology
- Hospitals
- Food & Beverage
- Nanotechnology



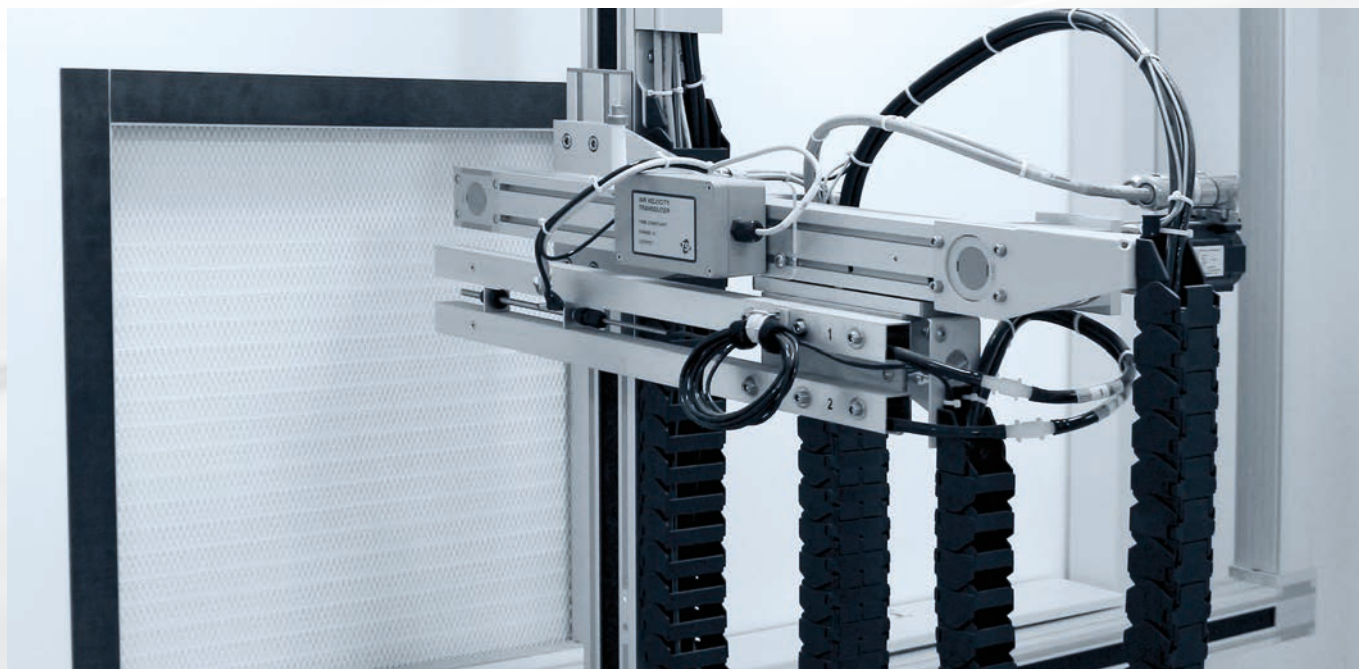


## FILTER CLASSIFICATION: EN 1822

Contaminants in air differ in size and affect different areas in a pharmaceutical process so classification of filters take a critical role. EPA, HEPA and ULPA filters are the main filter types for classification according to EN 1822 for filtration efficiency in Europe. HEPA and ULPA filters are also subject to individual tests. The international standard ISO 29463 is based on European standard EN 1822 and will probably replace this standard in the future. Both standards are based on the latest particle counting methods. The EN 1822 Standard involves efficient, high-efficient and ultra-low permeability air filters (EPA, HEPA, ULPA) used in ventilating and air-conditioning, cleanroom technologies or applications in nuclear and pharmaceutical industries. Their classification is based on the measuring of the size of particles (MPPS) passing to the clean side at a specific air speed.

| FILTER CLASSIFICATION | EFFICIENCY (%) @MPPS |             | PENETRATION (%) @MPPS |                   |
|-----------------------|----------------------|-------------|-----------------------|-------------------|
|                       | Overall Value        | Local Value | Overall Penetration   | Local Penetration |
| EN 1822               |                      |             |                       |                   |
| E10                   | 85                   | -           | 15                    | -                 |
| E11                   | 95                   | -           | 5                     | -                 |
| E12                   | 99.50                | -           | 0.5                   | -                 |
| H13                   | 99.95                | 99.75       | 0.05                  | 0.25              |
| H14                   | 99.995               | 99.975      | 0.005                 | 0.025             |
| U15                   | 99.9995              | 99.9975     | 0.0005                | 0.0025            |
| U16                   | 99.99995             | 99.99975    | 0.00005               | 0.00025           |
| U17                   | 99.999995            | 99.9999     | 0.000005              | 0.0001            |

EN 1822 reports must show average and local efficiency at the stated flow rate, initial pressure drop and class of the filter.



## CLEANROOM CLASSIFICATION: ISO 14644

Reduction of microbial contamination is vital in the design of a cleanroom. Mikropor follows ISO 14644, US 209E and EU GMP Directive 2017/1572 for classification and monitoring of cleanrooms where the contamination and particles need to be controlled.

A lower classification number means a higher level of cleanliness.

| STANDARDS    |                |              | PARTICLE COUNT                   |                                  |                                  |                                   |
|--------------|----------------|--------------|----------------------------------|----------------------------------|----------------------------------|-----------------------------------|
| US 209E 1992 | ISO 14644 1996 | BS 5295 1989 | 0,1 micron (per m <sup>3</sup> ) | 0,3 micron (per m <sup>3</sup> ) | 0,5 micron (per m <sup>3</sup> ) | 0,5 micron (per ft <sup>3</sup> ) |
| -            | CLASS 1        | -            | 10                               | -                                | -                                | -                                 |
| -            | CLASS 2        | -            | 100                              | 10                               | -                                | -                                 |
| 1            | CLASS 3        | C            | 1000                             | 102                              | 35                               | 1                                 |
| 10           | CLASS 4        | D            | 10000                            | 1020                             | 353                              | 10                                |
| 100          | CLASS 5        | E/F          | 100000                           | 10200                            | 3530                             | 100                               |
| 1000         | CLASS 6        | G/H          | 1000000                          | 102000                           | 35300                            | 1000                              |
| 10000        | CLASS 7        | J            | -                                | -                                | 353000                           | 10000                             |
| 100000       | CLASS 8        | K            | -                                | -                                | 3530000                          | 100000                            |

| CLEANROOM STANDARD |                | MAXIMUM PERMITTED NUMBER OF PARTICLES /M <sup>3</sup> |                |                     |                     | EXAMPLES OF OPERATIONS FOR TERMINALLY STERILISED PRODUCTS                | EXAMPLES OF OPERATIONS FOR ASEPTIC PREPARATIONS |
|--------------------|----------------|---|----------------|---------------------|---------------------|--|---|
| EU GMP Grade       | ISO EN 14644-1 | At Rest ≥0.5µm  | At Rest ≥5.0µm | In Operation ≥0.5µm | In Operation ≥5.0µm |  |   |
| A                  | 5              | 3.520   | 20             | 3.520               | 20                  | Filling products, when unusually at risk                                 | Aseptic preparation and filling                 |
| B                  | 5              | 3.520   | 29             | 352.000             | 2.900               |  |   |
| C                  | 7              | 352.000   | 2.900          | 3.520.000           | 29.000              | Preparation of solutions, when unusually at risk.<br>Filling of products | Preparation of solutions to be filtered         |
| D                  | 8              | 3.520.000   | 29.000         | Not defined         | Not defined         | Preparation of solutions and components for subsequent filling           | Handling of components after washing            |

# A FILTER YOU CAN TRUST

Air Quality is critical in injectable and infusion production zones: these areas must remain free of contaminants. A leak free EPA, HEPA or ULPA filter of high efficiency plays an important role in fulfilling the hygienic requirements and help optimize the differential pressure between zones.

## How can you check a high quality manufactured HEPA filter before installation and during operation?

### INSTALLATION

- Correct and solid packing
- Proper labelling with a serial number for traceability
- Individual test report in accordance with EN1822-4
- Suitable gasket for existing HEPA Box or ceiling detail
- No visual damage on filter media, frame or gasket

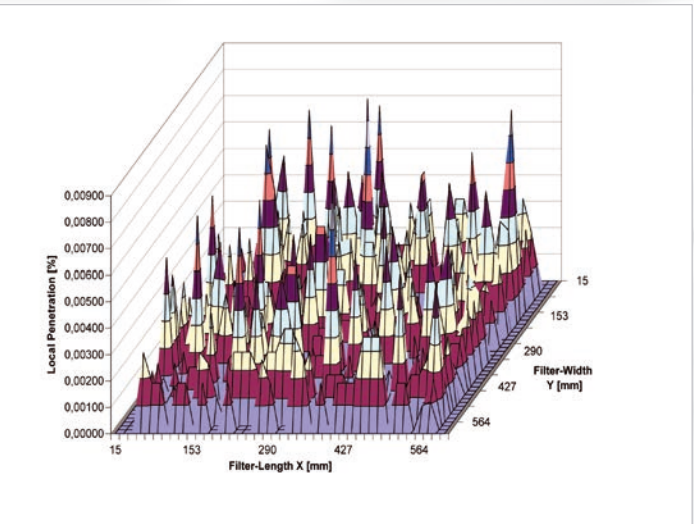
### OPERATION

- Successful filter scan test and integrity result
- Matching initial differential pressure drop with specification

### PERFORMANCE

- Consistent particle efficiency over time
- Leakage free performance of media and gasket over time

|   |  |   |  |
|---|--|---|--|
| TOPAS   |  |   |  |
| Prüfbericht nach EN 1822-4  |  |   |  |
| Test report according to EN 1822-4  |  |   |  |
| Rapport de test selon EN1822-4  |  |   |  |
| Rücksetzen / Reset / RAZ  |  |   |  |
| Filterdaten / Filter data / Filtré techniques   |  |   |  |
| Filternummer<br>Production lot<br>Numero de production  | Filternummer<br>Filter no.<br>Numero de filtre   | Mediumcharge<br>Medium lot no.<br>Numero de lot de medium | Test Datum<br>Date of test<br>Date de test   |
| HFN-610/610/70-13PD   | 1259   | 2009-02-25  | op.  |
| Nennabmessung (B x L x T)<br>Filter dimensions (B x L x T)<br>Dimensions du filtre (B x L x T)  |  |   |  |
| 610 x 610 x 70mm  | 800  | HEPA H13  |  |
| Minimale integrale Abschnegegrad<br>Minimum integral efficiency<br>Minimum efficacité intégrale | Minimale totale Abschnegegrad<br>Minimum total efficiency<br>Minimum efficacité totale | g0.995  | 0.20µm   |
| 99.95000%   | 99.75000%  |   |  |
| Prüfbedingungen / Test Conditions / Conditions de test  |  |   |  |
| Prüfstromstrom<br>Test flow rate<br>Débit de test   | Substrat<br>Test aerosol<br>Aérosol de test  | Partikelgröße<br>Particle size<br>Taille de particule     | Prüfkonzentration<br>Load concentration<br>Concentration amont   |
| 799.8m³/h   | DEHS   | 0.10 - 0.56µm   | 8.02E+2/cfcm³  |
|   |  | 16.1°C  | 37.9%  |
| Prüfergebnisse / Test Results / Résultats de test   |  |   |  |
| Integrierte Abschnegegrad<br>Integral efficiency<br>Efficacité intégrale                        | Minimale Abschnegegrad<br>Minimum efficiency<br>Minimum efficacité                     | Druckverlust<br>Pressure drop<br>Perte de charge          | Klassifizierung gemäß Testergebnis<br>Classification to test result<br>Classification selon résultat de test |
| 99.99870%   | 99.99855%  | 196Pa   | HEPA H13   |
| Anzahl der gefundenen Leckstellen<br>Number of leaks detected<br>Nombre de fuites détectées     | Lecktest gemäß EN1822-4<br>Leakage test to EN 1822-4<br>Test de fuite selon EN 1822-4  |   |  |
| 0   | bestanden / passed / accepté   |   |  |
| Lecksignal / Leak signal / Signal du fuite  |  |   |  |
| Signalabstand / Signal difference / Signal difference   |  |   |  |
| 99  |  |   |  |





## BEST HEPA FILTERS ALSO NEED GOOD PRE-FILTRATION

Correct combination of filtration stages reduces overall air flow resistance and keeps pressure drops lower for longer. This reduces the energy consumption of fans and leads to a more energy efficient system.

Typically, three stage filtration: a G4 panel filter, an M class 2<sup>nd</sup> stage and a fine filter is used as pre filtration of a high efficient HEPA filter. A rigid type MPR pocket filter can be used as a pre filter instead of a G4 panel and an M class filter combination. MPR filters offer optimum combination of high dust holding capacity, coarse & fine dust arrestance, low pressure drop and long life time. Mikropor recommends MPG or MVEE type fine filters for pharmaceutical applications in order to make additional energy savings.



With its energy efficient filters, Mikropor protects your health and the environment while allowing you to save money.

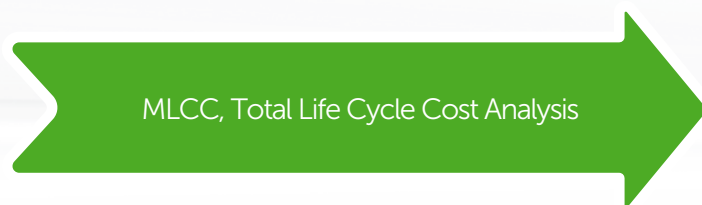
With customer demands and long-term cost reductions in mind, **MIKROPOR CLEAN AIR MANAGEMENT (MICAM)**, the total filter management system focused on long term cost reduction, filter life cycle optimization and improved air quality, was created.

## MICAM STEPS

### FULL SITE AUDIT



### REPORTING & OPTIMIZATION



### ON SITE TECHNICIAN



## MIKROPOR SOLUTIONS

With more than 20 years of Global Filtration experience as a World Class Manufacturer utilizing state of the art technologies and equipment, Mikropor understands its customers' demands and thus is the preferred partner of pharmaceutical manufacturers worldwide.

### MSKPN SERIES

|                       |  |
|-----------------------|--|
| Media                 | Synthetic  |
| Frame                 | Plastic (ABS), Galvanized Steel, Stainless Steel |
| Final Pressure Drop   | 250 Pa   |
| Operating Temperature | 80°C   |
| Filter Efficiency*    | G4   |
| Filter Class**        | ISO Coarse                                       |
| Sealant               | Polyurethane                                     |
| Separators            | Thermoplastic Adhesive                           |
| Gasket                | Optional   |

#### Applications

- Primary filtration

#### Advantages

- Tidy pleat spacing
- Light and rigid filter
- Leakage free



### MPG SERIES

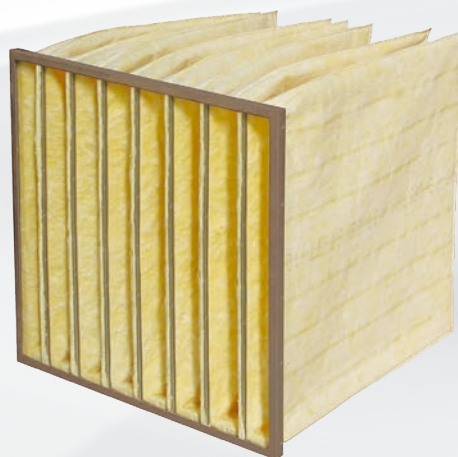
|                       |   |
|-----------------------|---|
| Media                 | Glassfiber                                    |
| Frame                 | Galvanized Steel                              |
| Final Pressure Drop   | 450 Pa  |
| Operating Temperature | 80°C  |
| Filter Efficiency*    | M5-M6-F7-F8                                   |
| Filter Class**        | ISO ePM10 / ISO ePM1                          |
| Media Color           | M5: White / M6: Green / F7: Pink / F8: Yellow |
| Fiber Assembly Type   | Sewn  |

#### Applications

- HVAC
- Pre-filter of absolute filters

#### Advantages

- Low initial pressure drop
- Low energy use



\* According to EN 779:2012    \*\* According to ISO 16890



## MPR SERIES

|                              |                        |
|------------------------------|------------------------|
| <b>Media</b>                 | Synthetic              |
| <b>Frame</b>                 | Molded Plastic Frame   |
| <b>Final Pressure Drop</b>   | 450 Pa                 |
| <b>Operating Temperature</b> | 80°C                   |
| <b>Filter Efficiency*</b>    | G4-M5-M6               |
| <b>Filter Class**</b>        | ISO Coarse - ISO ePM10 |

### Applications

- Automotive industry
- Gas turbine air intake systems
- General ventilation and air conditioning for office buildings, industrial environments, food processing facilities and laboratories

### Advantages

- High dust holding capacity
- Low initial pressure drop
- Rigid self-supporting pocket filter
- Incinerable



## MVEE SERIES

|                              |                  |
|------------------------------|------------------|
| <b>Media</b>                 | Microglass Fiber |
| <b>Frame</b>                 | PS               |
| <b>Final Pressure Drop</b>   | 450 Pa           |
| <b>Operating Temperature</b> | 80°C             |
| <b>Filter Efficiency*</b>    | F7-F8-F9         |
| <b>Filter Class**</b>        | ISO ePM1         |
| <b>Gasket</b>                | Optional         |
| <b>Sealant</b>               | Polyurethane     |
| <b>Separators</b>            | Hot Melt         |
| <b>Header Thickness</b>      | 20 mm, 25 mm     |

### Applications

- HVAC
- Cleanroom applications

### Advantages

- A Energy saver
- High surface area
- High efficiency



\* According to EN 779:2012    \*\* According to ISO 16890    \*\*\* According to Eurovent 4/21-2014

## MVHHT SERIES

|                     |                                     |
|---------------------|-------------------------------------|
| Media               | Micro Glass Fiber                   |
| Separators          | Micro Glass Fiber                   |
| Frame               | Stainless Steel or Galvanized Steel |
| Sealant             | Silicone                            |
| Temperature Max     | 250°C                               |
| Final Pressure Drop | 600 Pa                              |

### Applications

- Air conditioning systems
- Industrial processes



 **250°C**

## HFN SERIES ALUMINIUM PROFILE 70 mm

|                       |                                 |
|-----------------------|---------------------------------|
| Media                 | Microglass Fiber                |
| Frame                 | Extruded Anodized Aluminium     |
| Final Pressure Drop   | 600 Pa                          |
| Operating Temperature | 80°C                            |
| Filter Efficiency**** | E10-U15                         |
| Gasket                | Half Round Endless Polyurethane |
| Protection Grids      | Painted Aluminium on Both Sides |
| Separators            | Hotmelt                         |

### Applications

- Air conditioning systems (Hospitals, Laboratories, Museums)
- Industrial processes (Pharmaceutical, Food, Microelectronics)



70 mm Aluminium Profile View

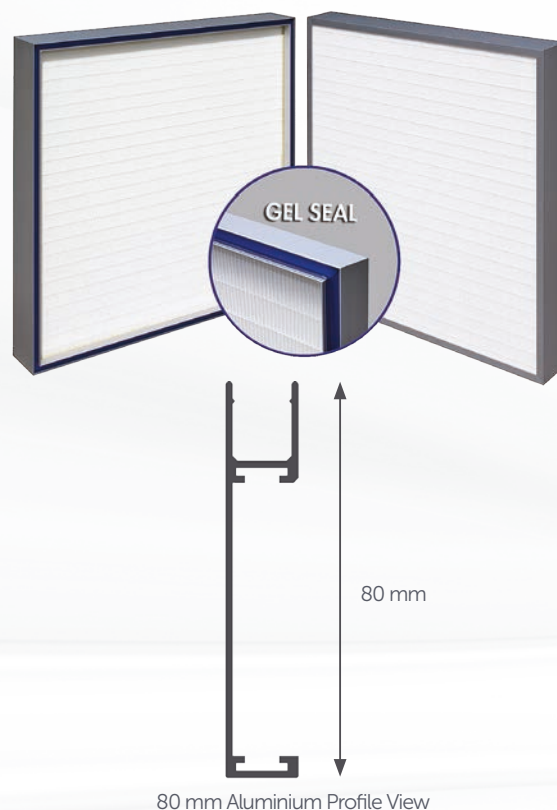
\*\*\*\* According to EN 1822

## HFN SERIES GEL SEAL 80 mm

|                              |                                 |
|------------------------------|---------------------------------|
| <b>Media</b>                 | Microglass Fiber                |
| <b>Frame</b>                 | Extruded Anodized Aluminium     |
| <b>Final Pressure Drop</b>   | 600 Pa                          |
| <b>Operating Temperature</b> | 80°C                            |
| <b>Filter Efficiency****</b> | E10-U15                         |
| <b>Gasket</b>                | Gel                             |
| <b>Protection Grids</b>      | Painted Aluminium on Both Sides |
| <b>Separators</b>            | Hotmelt                         |

### Applications

- Air conditioning systems (Hospitals, Laboratories, Museums)
- Industrial processes (Pharmaceutical, Food, Microelectronics)



## MVH SERIES METAL FRAME MAX. FLOW 292 mm

|                              |  |
|------------------------------|--|
| <b>Media</b>                 | Microglass Fiber                                 |
| <b>Frame</b>                 | Galvanized Steel, Aluminium, Stainless Steel     |
| <b>Final Pressure Drop</b>   | 600 Pa   |
| <b>Operating Temperature</b> | 80°C   |
| <b>Filter Efficiency****</b> | E10-H14  |
| <b>Gasket</b>                | Flat Neoprene or Half Round Endless Polyurethane |
| <b>Protection Grids</b>      | Optional   |
| <b>Separators</b>            | Hotmelt  |

### Applications

- Air conditioning systems (Hospitals, Laboratories, Museums)
- Industrial processes (Pharmaceutical, Food, Microelectronics)

### Advantages

- Strong frame
- High flow applications



\*\*\*\* According to EN 1822



## MHH SERIES MICRO HOOD FILTER 150 mm

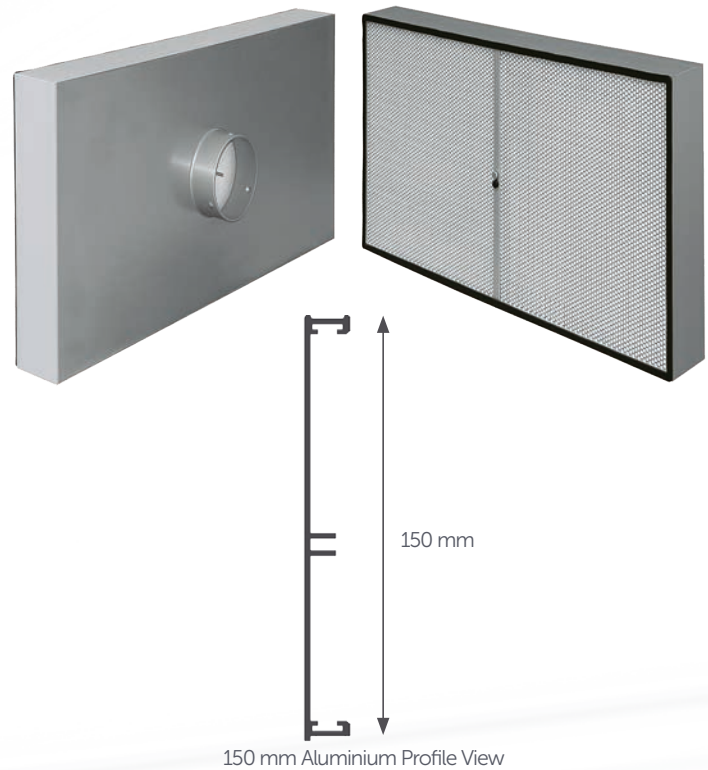
|                       |  |
|-----------------------|--|
| Media                 | Microglass Fiber                       |
| Frame                 | Extruded Anodized Aluminium            |
| Final Pressure Drop   | 600 Pa                                 |
| Operating Temperature | 80°C                                   |
| Filter Efficiency**** | E10-U15                                |
| Collar Dimensions     | 150 mm, 200 mm, 250 mm, 300 mm, 400 mm |
| Collar Height         | 65 mm                                  |
| Protection Grids      | Painted Aluminium on Downstream Side   |
| Separators            | Hotmelt                                |

### Applications

- Cleanroom applications
- Laminar flow cabins

### Advantages

- Adjustable air flow



## H-BOX LSC SERIES

### Applications

- Ceiling diffusers for terminal filtration
- Cleanroom applications

|                   |                           |
|-------------------|---------------------------|
| LSC               | Low side ceiling          |
| DSW               | Swirl diffusers           |
| D4D               | 4-direction diffusers     |
| DP                | Perforated diffusers      |
| Collar Dimensions | Ø150 mm, Ø200 mm, Ø250 mm |



\*\*\*\* According to EN 1822

# FILTRATION SOLUTIONS FOR PHARMACEUTICAL INDUSTRY



I. OSB Oguz Caddesi No: 5, 06935, Ankara-Turkey

☎ +90 312 267 0700 📠 +90 312 267 0552 ✉ mikropor@mikropor.com

🌐 📺 mikropor

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