

# MD8 Airscan®

Active sampling of airborne viruses, bacteria, yeasts and fungi

### **Product Information**

Monitoring ambient air in cleanrooms and controlled areas in the (c)GMP environment for viable microorganisms is a routine task in the pharmaceutical | biotechnology industry. As a rule, collection of data and subsequent analysis of the results permit trends to be recognized early and problems (OOS\*) with bioburden levels exceeding the limits to be prevented.

\*Out of specification



Active Air Monitoring in Cleanrooms and Controlled Areas Active monitoring of viable airborne microorganisms is an important instrument for ensuring product quality and safety. Sampling of at least 1 m³ of air is required by regulation standards. In this procedure, care must be taken that turbulence is not caused by, for example, devices such as active air samplers and that sampling is performed isokinetically.

The following areas need to be monitored using active sampling of airborne microorganisms:

In the pharmaceutical | biotechnology industry:

- Cleanrooms (grades A D; ISO classes 5 9)
- Sterility testing isolators
- Filling lines
- Controlled areas, e.g. quality control (QC) laboratories
- Warehouses | raw materials depots
- Personnel airlocks and aseptic transfer chambers for materials

### In the food and beverage industry:

- Manufacturing areas and production-related areas
- Quality control (QC) laboratories
- Warehouses | raw materials depots

### Diagnostics | Medicine:

- Cleanroom or controlled area
- Filling lines
- Manufacturing areas and production-related areas
- Quality control (QC) laboratories
- Warehouses | raw materials depots

### **Quality Control**

As Sartorius is a recognized supplier of products and services for the pharmaceutical industry, product quality and safety are its number one priorities. To meet stringent quality requirements, 100% final testing of the MD8 Airscan® is performed in manufacturing among the quality control checks carried out. In addition, every stainless steel sampling head is calibrated and adjusted after assembly.

## **Technical Specifications**

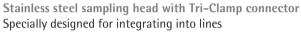
### Types of MD8 Airscan® Stainless Steel Sampling Heads

Stainless steel sampling head with bayonet connector Specially designed as a "stand-alone" version"

- Type of connector: Bayonet
- Flow capacity: Maximum flow rate capacity: up to 7 m³/h; adjustable in increments of 0.1 m³/h
- Saves the calibration data and actively regulates air flow
- Order number for sampling head: 16746-01--SHB
- Order number for bayonet package version: 16746SHBCOM

### Contents of package version:

- Command unit with 3 m connecting cable
- Stainless steel sampling head with bayonet flange connector
- Aluminum filter holder\*



- Type of connector: Tri-Clamp, 50.5 (TC 50.5)
- Maximum flow rate capacity: up to 7 m³/h; adjustable in increments of 0.1 m³/h
- Saves the calibration data and actively regulates air flow
- Order number for sampling head: 16746-01--SHT
- Order number for Tri-Clamp package version: 16746SHTCOM

### Contents of package version:

- Command unit with 3 m connecting cable
- Stainless steel sampling head with Tri-Clamp connector
- Stainless steel adapter, for connection of TC 50.5 to filter holder
- Aluminum filter holder\*

### MD8 Airscan® Command Unit

- Plastic material PA6 with 30% glass fiber
- RS-232 interface port for connecting a printer
- 2 status LEDs for displaying operating status and errors
- Stores the test results
- Order number of the command unit: 16746-01--COM







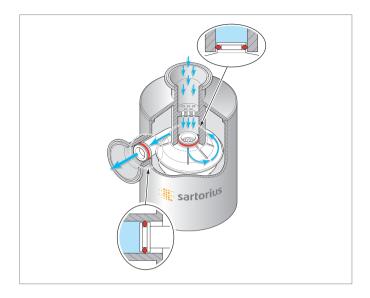
<sup>\*</sup>The filter holder is also available in an AISI 316L stainless steel version (German equivalent standard 1.4404).

### **Disinfection** | Sterilization

- Stainless steel sampling heads (bayonet and TC versions)
- IPA (70%)
- Ethanol (70%)
- Peracetic acid (1%)
- Dismozon® (1%)
- Sodium hypochlorite (5%)
- Formaldehyde (4%)
- Flowpath can be disinfected or sterilized | inline with vaporized hydrogen peroxide

### **Command unit**

- IPA (70%)
- Ethanol (70%)
- Peracetic acid (1%)
- Dismozon<sup>®</sup> (1%)
- Sodium hypochlorite (5%)
- Formaldehyde (4%)



# Specifications of the Stainless Steel Sampling Heads, Bayonet and TC Versions

Electropolished stainless steel: AISI 316L
 (German equivalent standard) 1.4404 or better

### **General Information**

|  | Unit        | Sampling Head with<br>Bayonet Connector                       | Sampling Head with Tri-Clamp<br>Connector (TC 50.5) |
|--|-------------|---|---|
| Dimensions $(L \times W \times H)$     | mm   inches | $128 \times 112 \times 137 \mid \sim 5 \times 4.4 \times 5.4$ | 128×112×154   ~5×4.4×6                              |
| Weight                                 | kg   Ib     | 2.6   ~6  | 2.6   ~6  |
| Power supply                           |             |   |   |
| Only through MD8 Airscan® command unit |             |   |   |
| Material                               |             |   |   |
| Gaskets                                |             | Silicone  | Silicone  |
| Surfaces                               |             | Stainless steel   | Stainless steel                                     |

### **Ambient Conditions**

|  | Unit                                     | Specification    |
|--|--|------------------|
| Installation site  |  |                  |
| Usual laboratory spaces and cleanrooms as defined by ISO 5 to ISO 9; use in controlled areas: Cleanroom classification A-D | m above sea level<br>ft. above sea level | <3,000<br><9,843 |
| Required clearance for air exhaust outlet  | mm   inches                              | >100   4         |
| Ambient temperature  |  |                  |
| Operation  | $^{\circ}\mathrm{C}$                     | 4 – 40           |
| Storage and transportation   | °C                                       | 4 – 45           |

## Specifications of the Stainless Steel Sampling Heads, Bayonet and TC Versions

|   | Unit  | Specification |
|---|-------|---------------|
| Max. temperature of motor in the sampling head  | °C    | 65            |
| Relative humidity   |       |               |
| Operation   | %     | 50 – 80       |
| Storage   | %     | 20-90         |
| Electromagnetic compatibility according to DIN EN 61326-1:<br>Electrical equipment for measurement, control and laboratory use – EMC requirements –<br>Part 1 |       |               |
| Defined immunity to interference: Suitable for use in industrial areas  |       |               |
| Limitation of interference  | Class | В             |

## **Command Unit Specifications**

## **Technical Specifications**

### **Dimensions and Weight**

|                    | Unit        | Specification             |
|--------------------|-------------|---------------------------|
| Dimensions (L×W×H) | mm   inches | 282×102×107  <br>11×4×4.2 |
| Weight             | kg   Ibs    | 1.4   ~3.1                |

### **Ambient Conditions**

|   | Unit                                     | Specification      |
|---|--|--------------------|
| Installation site   |  |                    |
| Usual laboratory spaces and cleanrooms as defined by ISO 5 to ISO 9; use in controlled areas: Cleanroom classification grades A-D                             | m above sea level<br>ft. above sea level | < 3,000<br>< 9,843 |
| Required clearance for air exhaust outlet   | mm   inches                              | > 100   4          |
| Ambient temperature   |  |                    |
| Operation   | °C                                       | 4 – 40             |
| Storage and transportation  | °C                                       | 4 – 45             |
| Max. temperature of motor in the sampling head  | °C                                       | 65                 |
| Relative humidity   |  |                    |
| Operation   | %  | 50 – 80            |
| Storage   | 0/0                                      | 20 – 90            |
| Electromagnetic compatibility according to DIN EN 61326-1:<br>Electrical equipment for measurement, control and laboratory use – EMC requirements –<br>Part 1 |  |                    |
| Defined immunity to interference: Suitable for use in industrial areas  |  |                    |
| Limitation of interference  | Class                                    | В                  |

### **Measurement Parameters**

|   | Unit  | Specification |
|---|-------|---------------|
| Adjustable volume: adjustable in increments of 0.01 m <sup>3</sup>  |       |               |
| For gelatin membrane filters  | $m^3$ | 0.01 – 9.99   |
| For cellulose nitrate membrane filters                              | $m^3$ | 0.01 – 1.10   |
| Adjustable air flow: adjustable in increments of 0.1 m <sup>3</sup> |       |               |
| With gelatin membrane filters                                       | m³/h  | 1.8 – 7       |
| With cellulose nitrate membrane filters                             | m³/h  | 1.8 – 3       |

### Interfaces

RS-232 interface port for connecting a printer

Suitable printer: Sartorius YDP30 (baud: 9600; parity: odd; data bit: 8; stop bit: 1)

### **Power Supply**

| Power Supply Unit   | Unit                                  | <b>Rating Specification</b> |
|---|---------------------------------------|-----------------------------|
| Type: Sartorius power supply, model 1000018304  |                                       |                             |
| Primary   |                                       |                             |
| Voltage   | $V_{AC}$                              | 100 – 240 ±10%              |
| Frequency   | Hz                                    | 50 – 60                     |
| Power consumption, max.   | A                                     | 2.0                         |
| Secondary   |                                       |                             |
| Voltage   | $V_{DC}$                              | 24 ±5%                      |
| Power, max.   | A                                     | 6.25                        |
| Short-circuit protection: Electronic  |                                       |                             |
| Protection class according to DIN EN/IEC 60950-1  |                                       | 1                           |
| Installation site according to DIN EN/IEC 60529-1   | m above sea level ft. above sea level | <3,000<br><9,843            |
| Installation category (overvoltage) according to IEC 60950-1  |                                       | II                          |
| Contamination level according to IEC 60950-1  |                                       | 2                           |
| Connecting cable for power supply   | Class                                 | В                           |
| Connecting cable according to DIN EN/IEC 60320-1/C14: country-specific, 3-pin; can be plugged in at both ends |                                       |                             |
| Socket according to DIN EN/IEC 60320-1/C14: 3-pin   |                                       |                             |
| Additional data: See label on the power supply  |                                       |                             |

| Command Unit and Sampling Head                    | Unit     | <b>Rating Specification</b> |
|---|----------|-----------------------------|
| Power supply for control unit:                    |          |                             |
| Only via Sartorius power supply, model 1000018304 |          |                             |
| Voltage   | $V_{DC}$ | 24 ±5%                      |
| Power consumption                                 | A        | 5.0                         |

Power supply for sampling head: Only through command unit

## **Ordering Information**

### **Recommended Accessories and Consumables**

### Accessories

This table shows a sampling of the range of accessories that can be ordered. Please contact Sartorius for information on additional products.

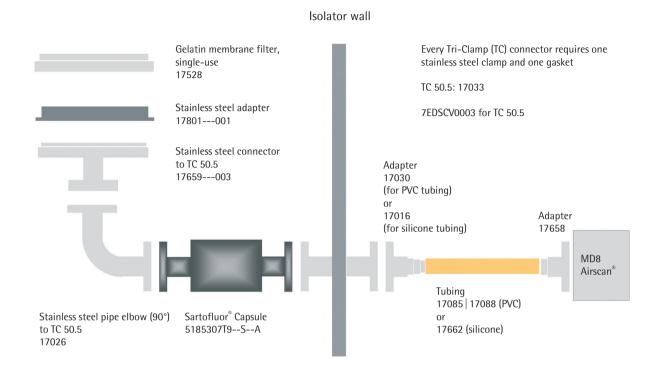
|    | Product   | Quantity | Order Number |
|----|---|----------|--------------|
|    | Adapter for gelatin membrane filter   | 1        | 17801        |
|    | Adapter, Tri-Clamp (TC 50.5) to bayonet, stainless steel  | 1        | 17659003     |
|    | Adapter, bayonet to Tri-Clamp (TC 50.5), stainless steel  | 1        | 1ZAD-0025    |
|    | Adapter, TC 50.5 to single-step DN 25 hose barbs, stainless steel. Can be used on the air outlet for conducting exhaust air outside the area. | 1        | 17016        |
| 12 | Clamp for 1" to 11/2" Sanitary flange   | 1        | 17033        |

### Consumables

This table shows a sampling of the range of consumables that can be ordered. Please contact Sartorius for information on additional products.

|    | Product   | Quantity | Order Number |
|----|---|----------|--------------|
| 00 | Gasket for Tri-Clamp TC 50.5 connector, silicone  | 2        | 7EDSCV0003   |
|    | Sartofluor <sup>®</sup> capsule, sterilizing-grade air filter, 0.2 μm, 0.2 m <sup>2</sup> filter area | 4        | 5181307T9SSA |
|    | PVC tubing, 2 m (~6.5 ft.)  | 1        | 17085        |
|    | PVC hose, 5 m (~16 ft.)   | 1        | 17088        |
|    | Silicone tubing, 1 m (~ 3.3 ft.)  | 1        | 17662        |
|    | Quick-connect cable   | 1        | 69898530     |
|    | Cable for YDP30 printer   | 1        | YCC01-0041M3 |

### Installation of the MD8 Airscan® | Isolator



### Sartorius Service

### We ensure the quality of your results

From equipment qualification  $IQ \mid OQ$  to regular maintenance: We offer you just the right choice of services to ensure that you comply with the high regulatory requirements right from the beginning, especially in GMP environments. Not only that: we will take care that your air sampler operates reliably over the long term.

Get more information at www.sartorius.com/service

### Europe

**Germany** Sartorius Lab Instruments GmbH & Co. KG Otto-Brenner-Strasse 20 37079 Goettingen

Phone +49.551.308.0 Fax +49.551.308.3289

#### France & Suisse Romande

Sartorius France 2. rue Antoine Laurent de Lavoisier ZA de la Gaudrée 91410 Dourdan

Phone +33.1.70.62.50.00 Fax +33.1.64.59.76.39

Sartorius Austria GmbH Modecenterstrasse 22 1030 Vienna

Phone +43.1.7965760.0 Fax +43.1.7965760.24

#### Belgium

Sartorius Belgium N.V. Rue Colonel Bourg 105 1030 Bruxelles

Phone +32.2.756.06.90 Fax +32.2.481.84.11

#### Finland & Baltics

Sartorius Biohit Liquid Handling Oy Laippatie 1 00880 Helsinki

Phone +358.9.755.951 Fax +358.9.755.95.200

#### Hungary

Sartorius Hungária Kft. Kagyló u. 5. 2092 Budakeszi

Phone +3623.457.227 Fax +3623.457.147

### Ireland

Sartorius Ireland Ltd. Unit 41. The Business Centre Stadium Business Park Ballycoolin Road Dublin 11

Phone +353.1.8089050 Fax +353.1.8089388

#### Italy

Sartorius Italy S.r.l. Via Torino 3/5 20814 Varedo (MB)

Phone +39.0362.5557.11 Fax +39.0362.5557.99

#### Netherlands

Sartorius Netherlands B.V.

Phone ±31 30 60 53 001 Fax +31.30.60.52.917

info.netherlands@sartorius.com

Sartorius Poland sp.z o.o. ul. Wrzesinska 70 62-025 Kostrzvn

Phone +48.61.6473830 Fax +48.61.6473839

#### **Russian Federation**

LLC "Sartorius RUS" Vasilyevsky Island 5th line 70, Lit. A 199178 St. Petersburg

Phone +7.812.327.53.27 Fax +7.812.327.53.23

#### Spain & Portugal

Sartorius Spain, S.A. Avda, de la Industria, 32 Edificio PAYMA 28108 Alcobendas (Madrid)

Phone Spain +34.913.586.095 Phone Portugal +351.800.855.800 Fax Spain +34.913.589.623 Fax Portugal +351.800.855.799

#### Switzerland

Sartorius Mechatronics Switzerland AG Ringstrasse 24a 8317 Tagelswangen (ZH)

Phone +41.44.746.50.00 Fax +41.44.746.50.50

Sartorius UK Ltd. Longmead Business Centre Blenheim Road, Epsom Surrey KT19 9QQ

Phone +44.1372.737159 Fax +44.1372.726171

### Ukraine

LLS "Sartorius RUS" Post Box 440 "B" 01001 Kiev, Ukraine

Phone +380.44.411.4918 Fax +380.50.623.3162

### **Americas**

#### IISA

Sartorius Corporation 5 Orville Drive, Suite 200 Bohemia, NY 11716

Phone +1.631.254.4249 Toll-free +1.800.635.2906 Fax +1.631.254.4253

#### Argentina

Sartorius Argentina S.A. Int. A. Ávalos 4251 B1605ECS Munro **Buenos Aires** 

Phone +54.11.4721.0505 Fax +54.11.4762.2333

Sartorius do Brasil Ltda Avenida Senador Vergueiro 2962 São Bernardo do Campo CEP 09600-000 - SP- Brasil

Phone +55.11.4362.8900 Fax +55.11.4362.8901

#### Canada

Sartorius Canada Inc 1173 North Service Road West, D4 Oakville, ON L6M 2V9

Phone +1.905.569.7977 Toll-Free +1.800.668.4234 Fax +1.905.569.7021

#### Mexico

Sartorius de México, S.A. de C.V. Libramiento Norte de Tepotzotlan s/n, Colonia Barrio Tlacateco, Municipio de Tepotzotlan, Estado de México, C.P. 54605

Phone +52.55.5562.1102 Fax +52.55.5562.2942

leadsmex@sartorius.com

#### Peru

Sartorius Peru S.A.C. Avenue Alberto del Campo 411 Floor 12 – The Office 15076 - San Isidro, Lima

Phone +51.1.441 0158 Fax +51.1.422 6100

## Asia | Pacific

#### Australia

Sartorius Australia Pty. Ltd. Unit 5, 7-11 Rodeo Drive Dandenong South Vic 3175

Phone +61.3.8762.1800 Fax +61.3.8762.1828

Sartorius (Shanghai) Trading Co., Ltd. 3rd Floor, North Wing, Tower 1 No. 4560 Jinke Road Zhangjiang Hi-Tech Park Pudong District Shanghai 201210, P.R. China

Phone +86.21.6878.2300 Fax +86.21.6878.2882

#### Hong Kong

Sartorius Hong Kong Ltd. Unit 1012. Lu Plaza 2 Wing Yip Street Kwun Tong Kowloon, Hong Kong

Phone +852.2774.2678 Fax +852.2766.3526

#### India

Sartorius Weighing India Pvt. Ltd. #69/2-69/3, NH 48, Jakkasandra, Nelamangala Tq 562 123 Bangalore, India

Phone +91.80.4350.5250 Fax +91.80.4350.5253

#### Japan

Sartorius Japan K.K. 4th Fl., Daiwa Shinagawa North Bldg. 8-11, Kita-Shinagawa 1-chome Shinagawa-ku, Tokyo, 140-0001 Japan

Phone +81.3.3740.5408 Fax +81.3.3740.5406

### Malaysia

Sartorius Malaysia Sdn. Bhd Lot L3-E-3B, Enterprise 4 Technology Park Malaysia Bukit Jalil 57000 Kuala Lumpur, Malaysia

Phone +60.3.8996.0622 Fax +60.3.8996.0755

#### Singapore

Sartorius Singapore Pte. Ltd 10 Science Park Rd The Alpha #02-13/14 Singapore Science Park II Singapore 117684

Phone +65.6872.3966 Fax +65.6778.2494

#### South Korea

Sartorius Korea Ltd. 8th Floor, Solid Space B/D, PanGyoYeok-Ro 220, BunDang-Gu SeongNam-Si, GyeongGi-Do, 463-400

Phone +82 31 622 5700 Fax +82.31.622.5799

#### Thailand

Sartorius (Thailand) Co. Ltd. 129 Rama 9 Road, Huaykwang Bangkok 10310

Phone +66.2643.8361-6 Fax +66.2643.8367