



Data Sheet

ClariCap® GS

Microglassfiber Capsule Filters

Pre-filtration is an important process requirement which helps protect sterilizing membrane filters, specially while filtering difficult to filter solutions.

Process owners are continuously looking for high efficiency filters, which not only help enhance the life of final membrane filters, but also can be used as final filters for clarification and polishing applications.

mdi ClariCap® GS Microglassfiber Capsule Filters are multilayered, high throughput filters, specially designed for turbid and difficult to filter solutions. The microglassfiber medium is designed to retain colloidal particles and for removal of deformable and non-deformable particles and microorganisms from liquids.

The polypropylene layer downstream of microglassfiber layers prevents media migration. The high dirt holding capacity, biochemical inertness, adsorption and high wet strength of the filtration medium makes it suitable for clarification and prefiltration of wide range of aqueous, non-aqueous and biologicals solutions.

ClariCap[®] GS microglassfiber capsule filters use **mdi** microglassfiber filter media in polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

The products are deeply validated for use in Biopharmaceutical applications and specially recommended for single use systems. ClariCap[®] GS are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities. Packaging is done in double polybags for convenience of taking ClariCap[®] in clean areas for making disposable assemblies for subsequent sterilization.

Applications

- Pre-filtration of high value difficult to filter drug solutions
- Precipitate removal in protein processing and plasma fractions
- Removal of un-dissolved buffer salts and cell culture media
- Prefiltration of serum and other viscous biologicals
- Polishing of turbid solution
- Chemical Processing
- Beverage clarification

Key Features

- Very high particulate retention efficiency
- High throughput
- High heat resistance
- Wide chemical compatibility
- No media migrating
- Biologically inert
- Easy installation
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability from a few ml to thousands of liters
- Sterilizable by Autoclaving or Ethylene Oxide

Quality Assurance

mdi quality management system emphasizes on quality by design rather by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each lot of capsule filter is accompanied by Certificate of Quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

ClariCap[®] *GS* filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

Bioburden Testing

Device bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Total Traceability

ClariCap[®] *GS* filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter lots.

These unique lot numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

ClariCap[®] *GS* filters are fitted with vent caps and are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics

Widest Range of End Connections

Biopharmaceutical processes involve transfer of high value fluids through multiple process steps. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the bio-processors.

mdi ClariCap® GS filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including EO sterilization and autoclaving.



1/2" HB



1/2" Single Stepped
Hose Barb



1/4" MNPT



1/4" SHB



Quick Connector



Male Luer Slip



3/8" Hose Barb



Female Luer Lock



1 1/2" Sanitary Flange



3/4" Sanitary Flange



1/2" MNPT



1" Hose Barb

Variety of end connections

Customized Connectivity

mdi ClariCap® GS filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in biopharmaceutical process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.



1 1/2" Sanitary Flange
to 1/2" Barb Hose



1 1/2" Sanitary Flange
to 3/4" Sanitary Flange



ClariCap® GS with HighSecurity
1/2" hose barb connection

Linear Upscaling from R&D to Production Process

mdi offers a wide range of *ClariCap® GS* filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 5 cm² to 10200 cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *ClariCap® GS* filters there by reducing the additional validation cost and time.



ClariCap® GS
25mm, 5cm²



ClariCap® GS
50mm, 20cm²



ClariCap® GS
1", 150cm²



ClariCap® GS
2", 400cm²



ClariCap® GS
5", 800cm²



ClariCap® GS
8", 1200cm²



ClariCap® GS
10", 3400cm²



ClariCap® GS
20", 6800cm²



ClariCap® GS
10", 10200cm²

| Filter Devices | EFA* (Nominal) | Hold up Volume |
|---------------------------|----------------------|----------------|
| <i>ClariCap® GS</i> 25 mm | 5cm ² | < 50µl |
| <i>ClariCap® GS</i> 50 mm | 20cm ² | < 200µl |
| <i>ClariCap® GS</i> 1" | 150cm ² | < 5ml |
| <i>ClariCap® GS</i> 2" | 400cm ² | < 25ml |
| <i>ClariCap® GS</i> 5" | 800cm ² | < 45ml |
| <i>ClariCap® GS</i> 8" | 1200cm ² | < 60ml |
| <i>ClariCap® GS</i> 5" | 1700cm ² | < 80ml |
| <i>ClariCap® GS</i> 10" | 3400cm ² | < 150ml |
| <i>ClariCap® GS</i> 20" | 6800cm ² | < 250ml |
| <i>ClariCap® GS</i> 30" | 10200cm ² | < 350ml |

*EFA: Effective Filtration Area

Construction

| | |
|---------------|------------------------------|
| Filter Media | Multilayered Microglassfiber |
| Plastic Parts | Polypropylene |

Size

| | | |
|---------------------------------|-------------------|--------------------|
| Size | 25 mm | 50 mm |
| EFA (Effective Filtration Area) | 5 cm ² | 20 cm ² |
| Operational Radius | 15 mm | 28 mm |

Operational

| | | |
|----------------------------|--|---|
| Max. Operating Temperature | 60 °C | |
| Max. Differential Pressure | 42 psi (3 Kg/cm ²) @ 30 °C | |
| Sterilization | By Autoclave | Autoclavable at 125 °C for 30 minutes, 30 cycles and it cannot be inline steam sterilized |
| | By Gas | Sterilizable by Ethylene Oxide |
| Shelf Life | 3 years after EO sterilization | |

Assurance

| | |
|---------------------------|---|
| Toxicity | Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics |
| Bacterial Endotoxin | Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release |
| Extractables with WFI | Passes NVR test as per USP <661> |
| Indirect Food Additives | Comply with USFDA 21 CFR Part 177.1520 |
| Oxidizable Substances | Within limits as specified in USP <1231> |
| Quality Management System | ISO-9001 Certified |
| USFDA | DMF No. 015554 |

Specifications

Small Capsule Filters

Datasheet

Construction

| | |
|---------------|------------------------------|
| Filter Media | Multilayered Microglassfiber |
| Plastic Parts | Polypropylene |

Size

| Size | 1" | 2" | 5" | 8" |
|---------------------------------|---------------------|---------------------|---------------------|----------------------|
| EFA (Effective Filtration Area) | 150 cm ² | 400 cm ² | 800 cm ² | 1200 cm ² |
| Operational Radius | 40 mm | 65 mm | 65 mm | 65 mm |

Operational

| | | |
|----------------------------|--|---|
| Max. Operating Temperature | 80 °C @ < 30 psi (2 Kg/cm ²) | |
| Max. Differential Pressure | 60 psi (4 Kg/cm ²) @ 30 °C | |
| Sterilization | By Autoclave | Autoclavable at 125 °C for 30 minutes, 30 cycles and it cannot be inline steam sterilized |
| | By Gas | Sterilizable by Ethylene Oxide |
| Shelf Life | 3 years after EO sterilization | |

Assurance

| | |
|---------------------------|---|
| Toxicity | Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics |
| Bacterial Endotoxin | Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release |
| Extractables with WFI | Passes NVR test as per USP <661> |
| Indirect Food Additives | Comply with USFDA 21 CFR Part 177.1520 |
| Oxidizable Substances | Within limits as specified in USP <1231> |
| Quality Management System | ISO-9001 Certified |
| USFDA | DMF No. 015554 |

Specifications

Large Capsule Filters

Construction

| | |
|---------------|------------------------------|
| Filter Media | Multilayered Microglassfiber |
| Plastic Parts | Polypropylene |

Size

| Size | 5" | 10" | 20" | 30" |
|---------------------------------|----------------------|----------------------|----------------------|-----------------------|
| EFA (Effective Filtration Area) | 1700 cm ² | 3400 cm ² | 6800 cm ² | 10200 cm ² |
| Operational Radius | 80 mm | 80 mm | 80 mm | 80 mm |

Operational

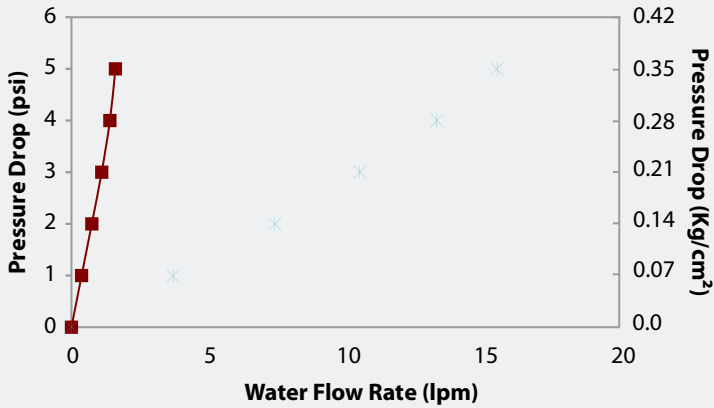
| | | |
|----------------------------|--|---|
| Max. Operating Temperature | 80 °C @ < 30 psi (2 Kg/cm ²) | |
| Max. Differential Pressure | 60 psi (4 Kg/cm ²) @ 30 °C | |
| Sterilization | By Autoclave | Autoclavable at 125 °C for 30 minutes, 30 cycles and it cannot be inline steam sterilized |
| | By Gas | Sterilizable by Ethylene Oxide |
| Shelf Life | 3 years after EO sterilization | |

Assurance

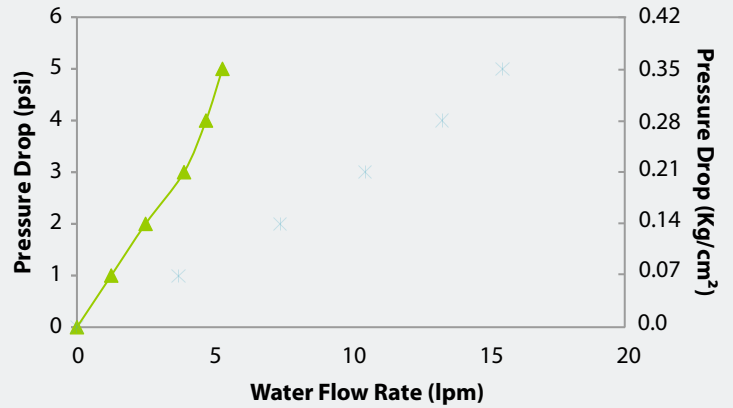
| | |
|---------------------------|---|
| Toxicity | Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics |
| Bacterial Endotoxin | Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release |
| Extractables with WFI | Passes NVR test as per USP <661> |
| Indirect Food Additives | Comply with USFDA 21 CFR Part 177.1520 |
| Oxidizable Substances | Within limits as specified in USP <1231> |
| Quality Management System | ISO-9001 Certified |
| USFDA | DMF No. 015554 |

Typical Water Flow Rates

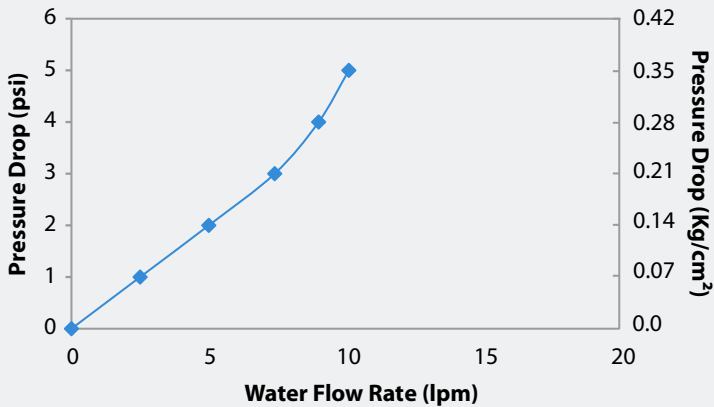
0.7 μm ClariCap[®] GS, 1" Capsule Filter



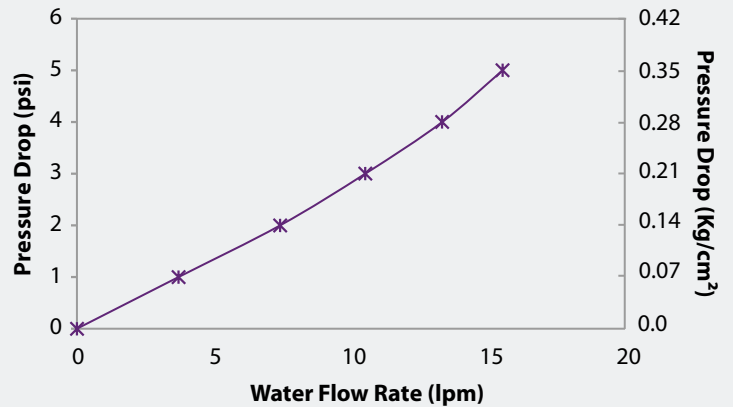
0.7 μm ClariCap[®] GS, 2" Capsule Filter



0.7 μm ClariCap[®] GS, 5" Capsule Filter



0.7 μm ClariCap[®] GS, 8" Capsule Filter



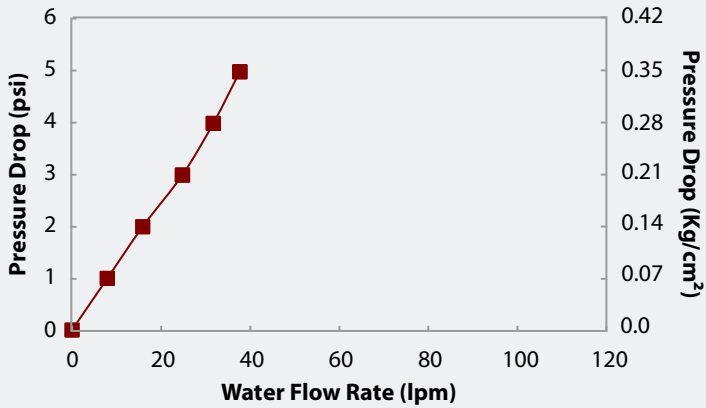
- 1 Inch Capsule Filters, DD Connection
- ▲ 2 Inch Capsule Filters, DD Connection
- ◆ 5 Inch Capsule Filters, DD Connection
- ✱ 8 Inch Capsule Filters, DD Connection

End Connection Type:

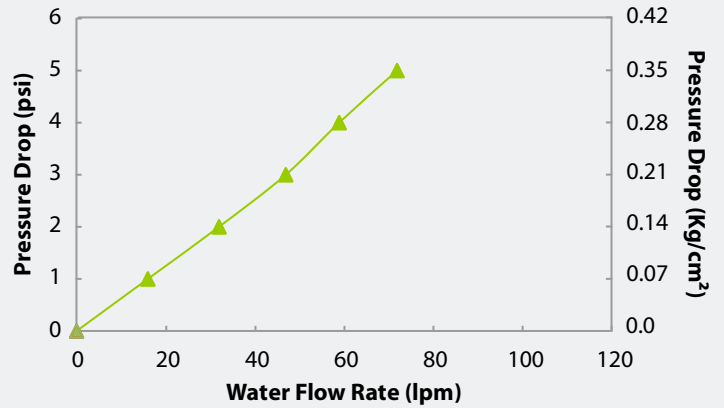
D: 1/2" Hose Barb

Typical Water Flow Rates

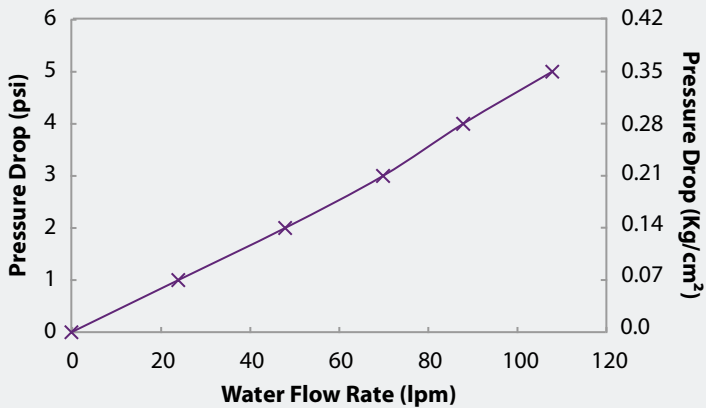
0.7 μm ClariCap[®] GS, 10" Capsule Filter



0.7 μm ClariCap[®] GS, 20" Capsule Filter



0.7 μm ClariCap[®] GS, 30" Capsule Filter



- 10 Inch Capsule Filters, EE Connection
- ▲ 20 Inch Capsule Filters, EE Connection
- × 30 Inch Capsule Filters, EE Connection

End Connection Type:

E: 1½" Sanitary Flange Connections

ClariCap® GS 25mm Inline Capsule filter

| Type | | Size | | Pore Size | | Inlet/Outlet | | X | X | Sterility | | Pack Size | |
|--------------|------|------|------|-----------|------|------------------|------|---|---|-------------|------|-----------|------|
| | Code | | Code | | Code | | Code | | | | Code | | Code |
| ClariCap® GS | IGSX | 25mm | 06 | 0.7µm | 41 | Female Luer Lock | M | | | Non Sterile | 1 | 100 | 04 |
| | | | | 1µm | 05 | Male Luer Slip | N | | | EO Sterile | 2 | | |
| | | | | 1.5µm | 14 | 1/8" Hose Barb | H | | | | | | |
| | | | | 2µm | 15 | 1/4" Hose Barb | B | | | | | | |

Example:

| | | | | | | | |
|------|----|----|----|---|---|---|----|
| IGSX | 06 | 41 | MN | X | X | 1 | 04 |
|------|----|----|----|---|---|---|----|

Example for Non Sterile: IGSX0641MNXX104

Example for EO Sterile: IGSX0641MNXX204

ClariCap® GS 50mm Inline Capsule filter

| Type | | Size | | Pore Size | | Inlet/Outlet | | X | X | Sterility | | Pack Size | |
|-----------------------------|------|------|------|-----------|------|----------------------|------|---|---|-------------|------|-----------|------|
| | Code | | Code | | Code | | Code | | | | Code | | Code |
| ClariCap® GS (without Vent) | IGSX | 50mm | 10 | 0.7µm | 41 | 1/4" SHB | B | | | Non Sterile | 1 | 10 | 02 |
| ClariCap® GS (with Vent) | VGSX | | | 1µm | 05 | 3/4" Sanitary Flange | S | | | EO Sterile | 2 | | |
| | | | | 1.5µm | 14 | Female Luer Lock | M | | | | | | |
| | | | | 2µm | 15 | | | | | | | | |

Example:

| | | | | | | | |
|------|----|----|----|---|---|---|----|
| VGSX | 10 | 41 | BB | X | X | 1 | 02 |
|------|----|----|----|---|---|---|----|

Example for Non Sterile: VGSX1041BBXX102

Example for EO Sterile: VGSX1041BBXX202

Inlet/Outlet Connections Available

| Inlet/Outlet | 25mm | 50mm | |
|-------------------------------|-------------|-----------|--------------|
| | | with Vent | without Vent |
| 1/4" - 3/4" Stepped Hose Barb | X | √ | X |
| 3/4" Sanitary Flange | X | √ | X |
| Female Luer Lock | Inlet Only | X | √ |
| Male Luer Slip | Outlet Only | X | X |
| 1/8" Hose Barb | √ | X | X |
| Male Luer Lock | Outlet Only | X | X |
| 1/4" Hose Barb | √ | X | X |

Dimension (Length) (in mm)

| Inlet/ Outlet | 25mm | 50mm |
|--|------|------|
| 1/4" - 3/8" Stepped Hose Barb I/O | - | 79 |
| 1/4" Single Step Hose Barb I/O | 38 | - |
| 3/4" Sanitary Flange I/O | - | 51 |
| Female Luer Lock Inlet/ Male Luer Slip Outlet | 23 | - |
| 1/8" Hose Barb I/O | 36 | - |
| Operational Radius | 15 | 28 |

Ordering Information

ClariCap® GS Small Capsule filter

| Type | | Size | | Pore Size | | Inlet/Outlet | | X | Bell | | Sterility | | Pack Size | |
|--------------|------|------|------|-----------|------|-----------------------------|------|---|-----------------|------|-------------|------|-----------|------|
| | Code | | Code | | Code | | Code | | | Code | | Code | | Code |
| ClariCap® GS | DGSX | 1" | 51 | 0.7µm | 41 | ¼" SHB | A | | Yes* | B | Non Sterile | 1 | | 01 |
| | | 2" | 52 | 1µm | 05 | ¼" MNPT (18 TPI) | B | | No Bell | X | EO Sterile | 2 | | |
| | | 5" | 53 | 1.5µm | 14 | ¼" BSP (19 TPI) | M | | Bell with cover | C | | | | |
| | | 8" | 57 | 2µm | 15 | ¼" BSP (19 TPI) with O-ring | P | | | | | | | |
| | | | | | | ¼" BSP | F | | | | | | | |
| | | | | | | ½" MNPT | C | | | | | | | |
| | | | | | | ½" Hose Barb | D | | | | | | | |
| | | | | | | 1½" Sanitary Flange | E | | | | | | | |
| | | | | | | ¾" Sanitary Flange | S | | | | | | | |
| | | | | | | Quick Connector | J | | | | | | | |
| | | | | | | ½" Single Step Hose Barb | Q | | | | | | | |
| | | | | | | Female Luer Lock | U | | | | | | | |
| | | | | | | Male Luer Slip | W | | | | | | | |
| | | | | | | ⅜" Hose Barb | N | | | | | | | |
| | | | | | | ⅝" Hose Barb | I | | | | | | | |

Example:

| | | | | | | | |
|------|----|----|----|---|---|---|----|
| DGSX | 57 | 41 | DD | X | X | 1 | 01 |
|------|----|----|----|---|---|---|----|

Example for Non Sterile: DGSX5141QQXX101

Example for EO Sterile: DGSX5141QQXX201

* Bell is available with

½" Hose Barb outlet connections in 1", 2", 5" and 8" capsule filters

¼" SHB outlet connection in 1" capsule filters only

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

| Inlet/Outlet | Size/Length | | | | Bell at outlet Available with (Size/outlet) | |
|-----------------------------|-------------|----|-------------|----|---|--|
| | 1" | 2" | 5" | 8" | | |
| ¼" Stepped Hose Barb | √ | √ | √ | √ | 1" / ¼" SHB | |
| ½" Single Step Hose Barb | X | √ | √ | √ | 1", 2", 5", 8" / ½" HB | |
| ½" Hose Barb | √ | √ | √ | √ | | |
| 1½" Sanitary Flange | √ | √ | √ | √ | | |
| ¾" Sanitary Flange | √ | √ | √ | √ | | |
| Quick Connector | √ | √ | √ | √ | | |
| ½" MNPT | X | √ | √ | √ | | |
| ¼" MNPT (18TPI) | √ | √ | √ | √ | | |
| ¼" BSP (19 TPI) | Inlet Only | X | X | X | | |
| ¼" BSP (19 TPI) with O-ring | Inlet Only | X | X | X | | |
| ¼" BSP | Inlet Only | √ | √ | √ | | |
| Female Luer Lock | √ | √ | √ | √ | | |
| Male Luer Slip | Outlet Only | X | X | X | | |
| ⅜" Hose Barb | √ | √ | Outlet Only | X | | |
| ⅝" Hose Barb | X | √ | √ | √ | | |

| Dimensions (in mm) | Small Capsule Filters | | | |
|--|-----------------------|-----|-----|-----|
| End Connections | 1" | 2" | 5" | 8" |
| ¼" SHB I/O | 94 | 122 | 172 | 223 |
| ¾" Sanitary Flange Inlet I/O | 85 | 104 | 155 | 206 |
| Quick Connector | 100 | 113 | 164 | 218 |
| 1½" Sanitary Flange I/O | 92 | 112 | 164 | 216 |
| ½" Hose Barb I/O | 90 | 112 | 162 | 214 |
| ½" Single Step Hose Barb I/O | - | 115 | 165 | 218 |
| 1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet | - | 112 | 165 | 216 |
| 3/8" Hose Barb I/O | - | 115 | 167 | 217 |
| Operational Radius | 40 | 65 | 65 | 65 |

