

Instructions for Use

Maxicaps[®] MR Virosart[®] HF, Max and Media



1000063447



SARTORIUS

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1 General Information

The following parts are required (order codes in brackets below) and must be ordered separately:

- 3 manual SU valve drives (3x BPRO202): re-usable
- 1 pressure safety device (1x 26787---PS): re-usable
- Pre-filter: single-use

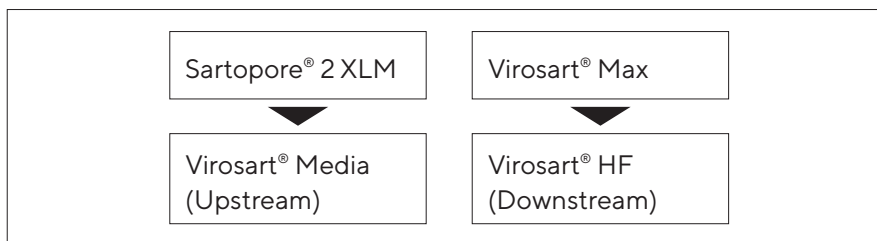


Fig. 1: Recommended pre-filter for the virus filter application

1.1 Intended Use

Maxicaps® MR Virosart® is an integrity testable single-use filtration system for pharmaceutical and biopharmaceutical production.

Please refer to the respective filter validation guide regarding the use of:

- Acids, Bases
- Inflammable fluids
- Oxidizing fluids

Maxicaps® MR Virosart® must be used for filtration of water based liquids only. Filtration of gas is prohibited for Maxicaps® MR Virosart® devices.

Maxicaps® MR Virosart® is a single-use device. The duration of usage should not exceed 48 hours.

1.2 Labeling

The filter type, pore size or retention rate are lasered on the filter housing. The remaining information lasered on the individual filter housings only refer to the individual filter capsules themselves and not to the complete Maxicaps® MR Virosart®.

The label on the plastic bag, the plastic holder of Maxicaps® MR Virosart® and the other packaging includes the product name, expiry date, gamma irradiation indicator (Virosart® HF and Media only) and batch number along with the order code.

1.3 In-Line Steam Sterilization

CAUTION

Risk of injury due to decreased pressure resistance of Maxicaps® MR Virosart® as a result of in-line steam sterilization! The reduced pressure resistance can lead to bursting of tubes, connections, or other system components if the system is pressurized. This can result in personal injury.

- Do **not** perform in-line steam sterilization or any other treatment that is not described in the instructions for use.
-

1.4 Maximum Operating Pressure

The maximum operating and integrity test pressure should not exceed 2.5 bar | 36 psi.

Since the max. pressure should never be exceeded the user must install a pressure safety device to protect the Maxicaps® MR Virosart® when used with pressurized gas (i.e. for integrity testing). Pressure safety device available from Sartorius (see chapter “10 Technical Data”, page 41).

⚠ CAUTION

Risk of injury due to exceeding the maximum operating pressure! Exceeding the maximum operating pressure can lead to bursting of tubes, connections, or other system components if the system is pressurized. This can result in personal injury.

- Before installation, making connections and before opening or closing the system, ensure that the system is depressurized.
 - Use a pressure indicator on Maxicaps® MR for pressure control throughout all process steps.
 - Use a flow rate indicator at the inlet side.
 - Do **not** exceed the maximum operating pressure.
-

1.5 Maximum Allowable Differential Pressure

In the direction of filtration

- at 20°C max. 2.5 bar | 36 psi

In the reverse direction of filtration

- at 20°C max. 1.0 bar | 14.5 psi for Maxicaps® MR Virosart® Media
- at 20°C max. 2.5 bar | 36 psi for Maxicaps® MR Virosart® HF
- at 20°C max. 0.5 bar | 7.3 psi for Maxicaps® MR Virosart® Max

⚠ CAUTION

Risk of injury due to non-compliance with operating pressure conditions! Deviating from safety precautions may cause bursting of tubes or system components, injuring people.

- Wear appropriate personal protective equipment.
 - Use a safety pressure device (Sartorius order code: 26787---PS) when connected to pressurized gas (see also chapter 10.1).
 - Do **not** put dry Maxicaps® MR Virosart® under gas pressure more than 1 bar | 14.5 psi.
 - For integrity testing:
 - Do **not** use gases other than air and nitrogen.
 - Do **not** perform on a dry Maxicaps® MR system.
-

1.6 Integrity Tests and Integrity Test Data

After wetting, Maxicaps® MR Virosart® can be integrity tested. It is highly recommended that testing is performed by an automatic integrity testing device like Sartochek®.

For the Maxicaps® MR Virosart® HF and Media the test conditons are:

Test pressure: 2.5 bar | 36 psi

Stabilization time: 5 min

Testing time: 5 min

Alarm values for the corresponding product:

3VI--28-MCG-MR2	≤ 41.0 mL/min
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3VI--28-MCG-MR3	≤ 60.0 mL/min
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3VI--28-MCG-MR4	≤ 79.0 mL/min
-----------------	---------------

3VI--28-MCG-MR5	≤ 99.0 mL/min
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3VI--28-MCG-MR6	≤ 117.0 mL/min
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3V2--28-IVG-MR3	≤ 48.0 mL/min
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3V2--28-IVG-MR6	≤ 97.0 mL/min
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For the Maxicaps® MR Virosart® Max the test conditons are:

Test pressure: 2.0 bar | 29 psi

Stabilization time: 5 min

Testing time: 5 min

Alarm values for the corresponding product:

54A7358N3--MR3	≤ 16.0 mL/min
54A7358N3--MR6	≤ 31.0 mL/min
54A7358N3--MR9	≤ 46.0 mL/min

For more information about single device integrity testing and product specific integrity test data, please refer to the respective validation guides of the single filter elements.

External mechanical impacts (e.g. falling, hitting against table edges) to any filter elements can cause micro-cracks that may not be visible to the naked eye, but can lead to destruction of the respective filter element when they are pressurized later. For this reason, filter elements may no longer be used once they have been subjected to such external mechanical impacts.

1.7 Use in a Suitably Protected Environment

If Maxicaps® MR Virosart® are intended to be pressurized during use, this may only take place in a suitably protected environment; additionally protective clothing and safety glasses must be worn.

1.8 Product Change

At minimum, the Maxicaps® MR Virosart® should be replaced at the latest, when the maximum allowable differential pressure is reached or when the validated process volume has been processed over the filter.

1.9 Application Support

If needed, please request the corresponding documents with further technical data, on how to carry out product integrity tests or special information about additional applications. Moreover, if you have specific questions about product validation, you can also contact our Validation Service or our Technical Support departments, they will be happy to assist you with all technical questions and optimization procedures.

1.10 Returning Used Filter Elements

Before returning used filter elements to Sartorius Stedim Biotech for additional testing, make sure that they have been sterilized and decontaminated properly. This has to be certified in the required Return Shipment Form that you can order from your local Sartorius Stedim Biotech representative. Otherwise, the provisions of the Employment Protection Act prohibit us from processing the returned products.

1.11 Liability

Sartorius Stedim Biotech does not assume liability if the filter devices are handled improperly.

In the interest of further developing Sartorius Stedim Biotech products, we reserve the right to make changes to the product.

Consider possible national regulations regarding use of pressure equipment.

2 General Product Description

Maxicaps® MR Virosart® is a single-use device for large scale virus filtration. Gamma-irradiatable filters can be delivered pre-sterilized but cannot be gamma irradiated multiple times.

The device includes either 2, 3, 4, 5 or 6 filters of 2.4 m² of process modules Virosart® HF filter elements, 3 or 6 of process modules 1.0 m² Virosart® Media or 3, 6 or 9 Maxicaps® filter elements 30" for Virosart® Max, which are connected in parallel. The venting is performed centrally through a dedicated venting line with a sterilizing grade venting filter.

Product Name	Order Code
Maxicaps® MR2 Virosart® HF	3VI--28-MCG-MR2
Maxicaps® MR3 Virosart® HF	3VI--28-MCG-MR3
Maxicaps® MR4 Virosart® HF	3VI--28-MCG-MR4
Maxicaps® MR5 Virosart® HF	3VI--28-MCG-MR5
Maxicaps® MR6 Virosart® HF	3VI--28-MCG-MR6

Product Name	Order Code
Maxicaps® MR3 Virosart® Media	3V2--28-IVG-MR3
Maxicaps® MR6 Virosart® Media	3V2--28-IVG-MR6

Product Name	Order Code
Maxicaps® MR3 Virosart® Max*	54A7358N3--MR3
Maxicaps® MR6 Virosart® Max*	54A7358N3--MR6
Maxicaps® MR9 Virosart® Max*	54A7358N3--MR9

* Please note that Maxicaps® MR Virosart® Max have been discontinued since end of 2023. Please find further information on the latest version of Maxicaps® MR Virosart® Max on our webpage www.sartorius.com.

The tubing sets of the Maxicaps® MR Virosart® allow either sterile connection via AseptiQuik®* G connectors or alternatively connection via 1 ½" Tri-Clamp connectors. For the use of the Tri-Clamp connector the sterile connector needs to be removed manually. Reinforced tubing is used for all tubing sets.

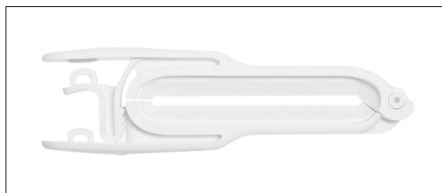
The tubing sets for the Maxicaps® MR Virosart® are constructed as following:

- Inlet connection: 2 AseptiQuik® with reinforced tubes
- Outlet connection: 2 AseptiQuik® with reinforced tubes (for Maxicaps® MR Virosart® HF an additional outlet with AseptikQuik® and flow restrictor is implemented)
- Venting connection: sterilizing grade venting filter with reinforced tube and gauge glass (applicable for the old vent line design) or with reservoir (applicable for the new vent line, see page 18)

The Maxicaps® MR is delivered with tube clamps either PharmaLok™*** from Nordson MEDICAL or Pure-Fit®*** from Saint-Gobain Performance Plastics. Please refer to the manufacturer's instructions for use of the respective tube clamp. Please pay attention to the remark on page 27 about positioning the tube in Pure-Fit® clamps.



Pure-Fit® tube clamp



PharmaLok™ tube clamp

* AseptiQuik® is a registered trademark of the Colder Products Company

** PharmaLok™ is a trademark of Nordson MEDICAL

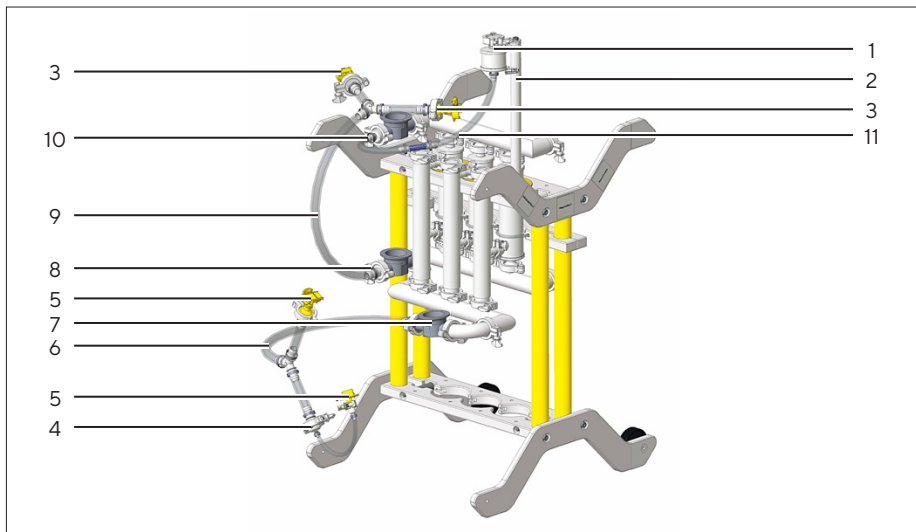
*** Pure-Fit® is a trademark of Saint-Gobain Performance Plastics

The temperature range for operation should be between 10°C | 50°F and 35°C | 95°F.

The integrity test can be done with an integrity testing device (Sartocheck®) by performing diffusion test. The integrity testing of the device is performed by connecting the Sartocheck® to the venting line (sterile testing) or inlet line (nonsterile testing).

Please read this manual carefully to correctly close | disconnect (with valve | clamp) the device prior to integrity testing!

3 Parts Overview



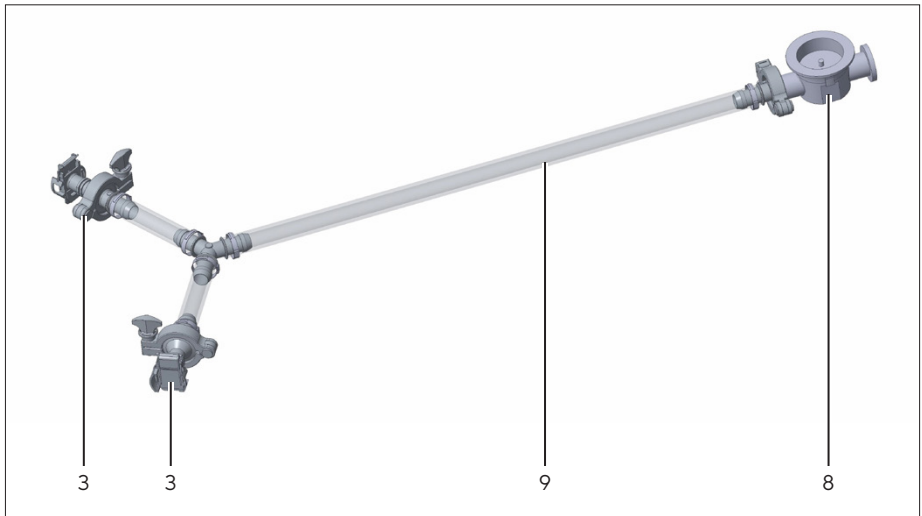
Pos.	Description
1	Air Filter (Sartopore® Air)
2	Air Filter Holder
3	Inlet (AseptiQuik® above Tri-Clamp)
4	The IT wetting kit is implemented for Virosart® HF only. When used for wetting, the kit ensures a defined back pressure needed for a successful IT testing.
5	Outlet (AseptiQuik® above Tri-Clamp)
6	Reinforced Silicon Tube $\frac{3}{4}$ " x $\frac{9}{8}$ " (ID x OD)
7	Outlet Valve
8	Inlet Valve
9	Reinforced Silicon Tube $\frac{3}{4}$ " x $\frac{9}{8}$ " (ID x OD)

Pos.	Description
10	Venting Line Valve
11	Venting Tubing Set**

* Manual valves to be ordered separately: Order No. BPR0202; SU Valve Actuator. 3 reusable actuators are needed for each Maxicaps® MR

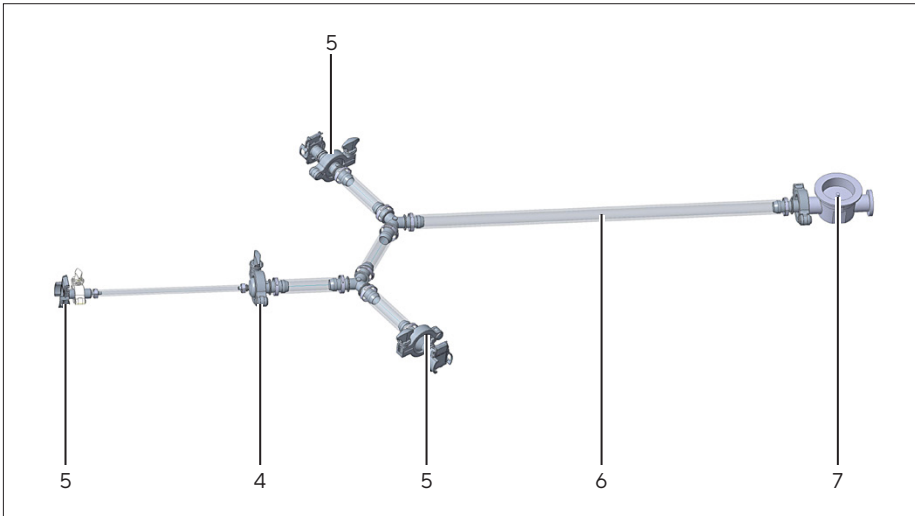
** Maxicaps® MR Virosart® (see page 11) are delivered with a new optimized venting line since February 2024, see chapter 3.4, page 18.

3.1 Inlet Tube



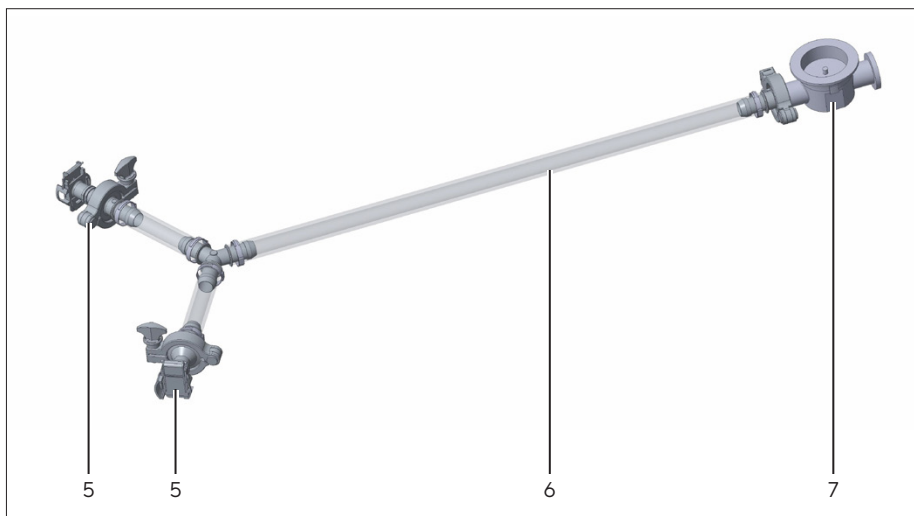
Pos.	Description
3	Inlet (2 AseptiQuik® G above 1 ½" Tri-Clamp)
8	Inlet Valve
9	Reinforced Silicon Tube ¾" x 9/8" (IDxOD)

3.2 Outlet Tube for Virosart® HF Filter



Pos.	Description
4	The IT wetting kit is implemented for Virosart® HF only. When used for wetting, the kit ensures a defined back pressure needed for a successful IT testing.
5	Outlet (2 AseptiQuik® G above 1½" Tri-Clamp and 1 AseptiQuik® above ¾" Tri-Clamp)
6	Reinforced Silicon Tube ¾" x ⅞" (ID x OD)
7	Outlet Valve

3.3 Outlet Tube for Virosart® Max and Media Filter



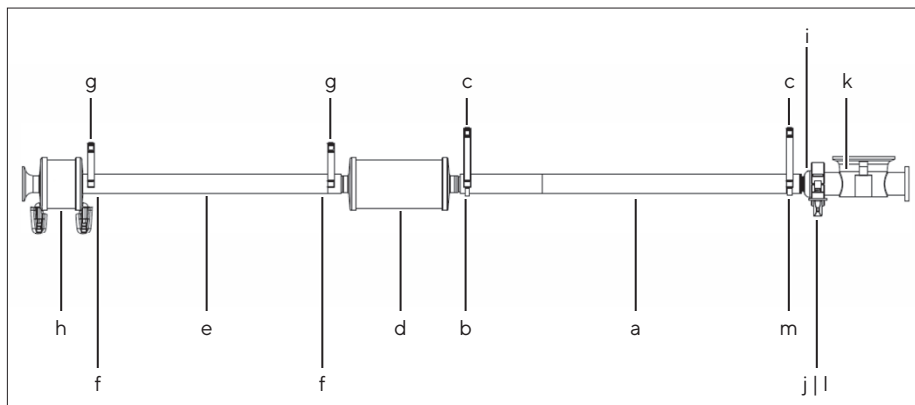
Pos.	Description
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5	Outlet (2 AseptiQuik® G above 1½" Tri-Clamp)
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6	Reinforced Silicon Tube ¾" x ⅞" (ID x OD)
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7	Outlet Valve
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3.4 Venting Tubing Set Maxicaps® MR Virosart® Max, Media and HF

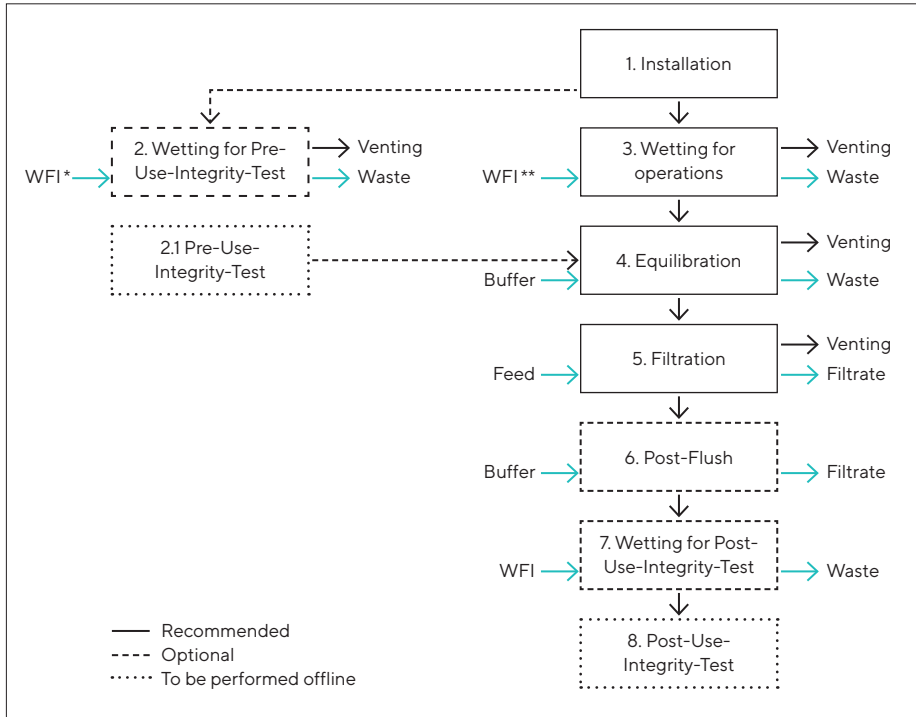


Pos.	Qty.	Description	Mat.-No.
a	1	Sanitech Tube $\frac{3}{4}$ " ID x $1\frac{1}{8}$ " OD (500 mm)	TU112962
b	1	Metal Ear Clamp D 33.1 mm W 7 mm T 0.6 mm	CT115119
c	2	Oetiker Clamp Protection Strap L	1000086961
d	1	Empty housing size 9 OO	1000103957
e	1	Sanitech Tube $\frac{1}{2}$ " ID x $\frac{7}{8}$ " OD (400 mm)	TU113136
f	2	Metal Ear Clamp D 24.5 mm W 7 mm T 0.6 mm	CT115255
g	2	Oetiker Clamp Protection Strap M	1000086819
h	1	Sartopore® Air G-MidiCaps® 0.2 μ m size 7	5195307A7G-SO--1
i	1	Adapter TC 50 x $\frac{3}{4}$ " HB	TR114166

Pos.	Qty.	Description	Mat.-No.
j	1	Molded Gasket for Maxi Flange	1000008171
k	1	Diaphragm Valve Size D TC 1"	BPR0016
l	1	Tri Clamp connection 1 ½"	TR100286
m	1	Metal Ear Clamp D 30.5 mm W 7 mm T 0.6 mm	CT115153

4 General Process Description

The virus filtration is typically performed in the following steps:



* For Maxicaps MR Viroart® Media: use IPA/WFI solution (v/v) (20:80) for pre-use integrity test

** For wetting the membrane of the Maxicaps MR Viroart® Media, use either WFI | buffer | cell culture media

5 Installation

Pallet hats are used to improve careful shipment and handling. Maxicaps® MR Virosart® packaging is qualified (ASTM D4169-09, DC 2, Assurance Level 2) to withstand a plane top load of at least 700 kg | 1543 lbs. An undamaged cardboard box is the main indicator for correct shipment.

5.1 Unpacking and Transfer to Clean Room

CAUTION

Risk of injury due to heavy weight of the Maxicaps® MR unit! When lifting and transporting the Maxicaps® MR unit, there is a risk of injury, e.g., as a result of the filter unit dropping or when lifted inappropriately.

- Get help from others when lifting and transporting the device or use a suitable lifting device.
-

1. Remove the cardboard packaging. Handle with care, avoid mechanical impact on the system.

2. Transfer Maxicaps® MR Virosart® in the horizontal position as indicated by the label on a roller cart into the air lock.



3. Inside the air lock carefully remove the outer plastic bag (one of the two). If using a cutter take extra care not to damage the underlying bag and the tubing of the device.
4. Pull the plastic bag down to floor. Lift one end of the Maxicaps® MR Virosart®, roll the bag out to the side, lift the other end pull bag away completely.



5. Transfer the Maxicaps® MR Virosart® into the clean room.
6. Inside the clean room remove the second plastic bag. Follow the same procedures as described above.



7. Be sure that the Maxicaps® MR Virosart® is upright: the air filter should be on top side and the wheels should stand on the ground. Remove all pink foam from the Maxicaps® MR Virosart®.



Fig.2: Before



Fig.3: After

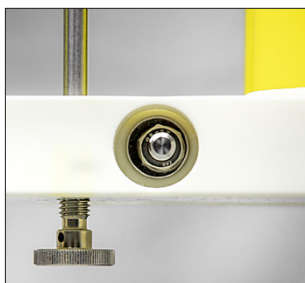
5.2 Installation Manual Actuators



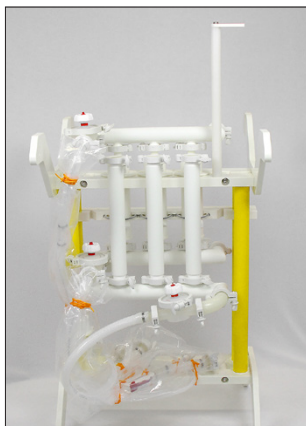
1. Install and fixate the manual actuator* of the diaphragm valve onto the inlet valve (8), venting line valve (10) and outlet valve (7). Please refer to the instructions for use of the GEMÜ® valve. After the installation, the GEMÜ® valves are slightly open. Please close all of the valves, as indicated by the arrows on the actuator.

* 3 reusable manual actuators are needed for the 3 SU valves. Order Code: BPR0202

5.3 Installation Air Filter Venting Line



1. Remove the transportation screw located at the bottom of the Maxicaps® MR Virosart®.



2. Remove the air filter line holder (2) and screw it in the thread on the top of the device. Please refer to the picture of the Maxicaps® MR Viroart® for correct placement of the air filter line holder (2).
3. Remove the packaging (the plastic bag and the orange cable ties) from the air filter and the venting line.



4. Fix the air filter line at the tube inlet in holder and secure with a cable tie if needed.



5. Remove the blind cap of the air filter Tri-Clamp (1). (This might be done at a later stage just before wetting). Please note that the updated vent line design uses an empty reservoir instead of the gauge glass, see new design in chapter 3.4, page 18.

Installation Inlet:



- ▶ Unpack inlet (3) and their tube sets, remove orange cable ties and packaging bag.

Installation Outlet:



- ▶ Unpack outlets (5) and their tube sets, remove orange cable ties and packaging bag.

How to correctly position tube clamps:

Position the tube in the middle of the clamp (do **not** follow the instructions of the Pure-Fit® clamp, which recommends tube positioning at the hinge side of the clamp).



Install the tube clamp either onto outlet (5) 1 for product or onto outlet (5) 2 for waste (for Virosart® HF use the outlet part with the flow restrictor (4) as waste line).

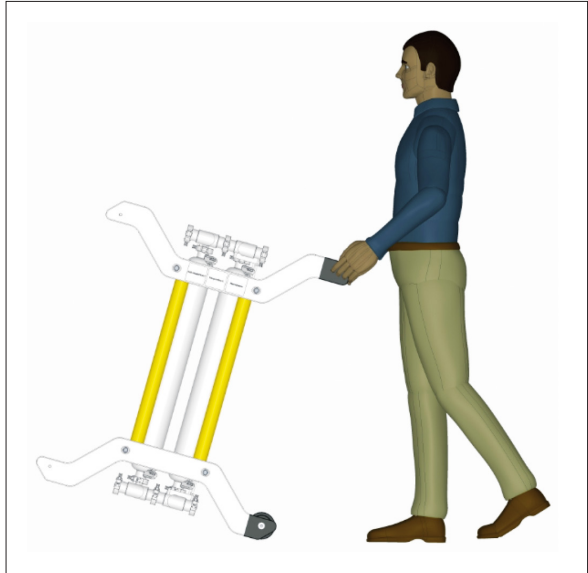
How to maintain sterility during operations:

Inlets (3) and Outlets (5) are sterile AseptiQuik® connections. Venting (1) is a Tri-Clamp connection. Opening the clamp and removing the blind cap at the venting will not lead to the loss of sterility as a sterile air filter will ensure sterility.

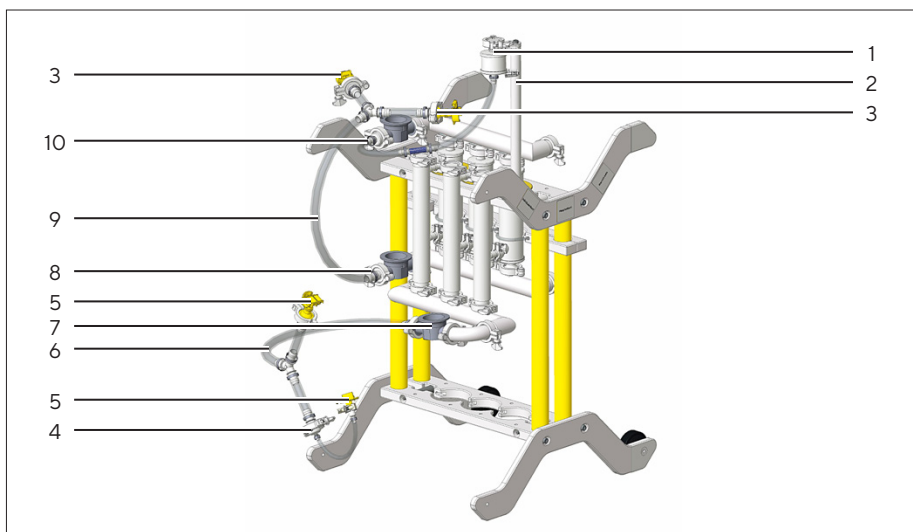
Removing the AseptiQuik® connectors from the Tri-Clamp connections of the system, on either the upstream or downstream side of the Maxicaps® MR Virosart®, will lead to loss of sterility of the device (for pre-sterilized Maxicaps® MR Virosart® only).

How to move Maxicaps® MR Viroart®:

Please have a look at the picture below to see how to move the Maxicaps® MR Viroart® easily.



6 Wetting & Equilibration



6.1 Filling and Venting

1. Connect the supply of the filling medium (e.g., WFI or buffer solution) to the Inlet (3) and put a tube clamp onto the other inlet line not in use. Make sure the supply is free of air.
2. Remove the Tri-Clamp blind cap from the sterile air filter (1).
3. Connect the receiving line to the outlet (5) for product and outlet (5) for waste. Place a tube clamp onto the outlet not in use (product line). For Virosart® HF use the outlet part with the wetting kit (4) as waste line.
4. Open venting line valve (10) slightly (2 turns).
5. Open the outlet valve (7).
6. Open inlet valve (8).

7. Fill up the device at a very low flow rate, e.g. 1–2 L/min or 0.1–0.2 bar | 1.45–2.9 psi inlet pressure in order to evacuate all air inside the dry Maxicaps® MR Virosart®. Observe the venting line carefully: when the liquid level goes up, close the venting line valve (10). **When the wetting liquid did pass the gauge glass (applicable for the old vent line design) or enters the reservoir (applicable for the new vent line) close the venting line valve (10) immediately.** Otherwise the fluid will immediately fill up the venting line, blocking the air evacuation. In case the venting line is filled up with fluid and no air is passing through: close supply; close the inlet valve (8). The system (including the venting line) is emptying through the opened outlet valve (7). After the venting line is emptied, open the inlet valve (8) and start the fluid supply again, controlling the flow parameters (as per above). The air is going out of the air filter (1).

The Maxicaps® MR Virosart® is filled. Continue to supply the filling fluid as described above.

6.2 Wetting & Equilibration for Maxicaps® MR Virosart® HF

1. For filling and proper wetting of the membrane use buffer | WFI. Follow instructions as described in chapter “6.1 Filling and Venting”. When the venting line valve (10) is closed increase to an inlet pressure of 2.4–2.5 bar | 34.8–36.2 psi. Flush for 10 min via the waste outlet (5) without the flow restrictor.
2. To evacuate remaining air from the inside of the Virosart® HF capsule, carefully open the vent valve once or twice during the flush. Carefully observe if air is still exiting via the vent line and do not allow liquid to reach the vent filter.
 - ▶ If no pre-use integrity test is performed, the filters are now flushed and ready to be used. Please continue with point 6.
 - ▶ If a pre-use integrity test is required the next steps need to be executed to ensure appropriate flushing prior to integrity testing.

3. Decrease the flow rate to 3 L/min or inlet pressure of 0.15 bar | 2.2 psi.
 4. Change to flushing with back-pressure by closing the outlet (5) with the tube clamp and flush via the second outlet part (5) with the pre-installed flow restrictor (4).
 5. Set the inlet pressure to 2.3 – 2.5 bar | 33.3 – 36.2 psi to create a differential pressure of 0.3 to 0.5 bar.
 - ▶ Flush the Maxicaps® MR2 and Maxicaps® MR3 Virosart® HF for 30 min.
 - ▶ Flush Maxicaps® MR4, Maxicaps® MR5 and Maxicaps® MR6 Virosart® HF for 40 min.
 - ▶ Observe the pressure at inlet: do **not** exceed 2.5 bar | 36 psi when filling through the inlet (3).
 6. After flushing for the defined time close the inlet valve.
 7. Drain filter by opening the vent and outlet valves. Facilitate draining by placing the outlet ports downwards if possible.
 8. Close all valves.
- ▷ After following this procedure the Maxicaps® MR Virosart® HF is wetted completely. The device is now ready for pre-use integrity testing.

6.3 Wetting & Equilibration for Maxicaps® MR Virosart® Max

For filling and proper wetting of the membrane use buffer | WFI. Follow instructions as described in chapter “6.1 Filling and Venting”.

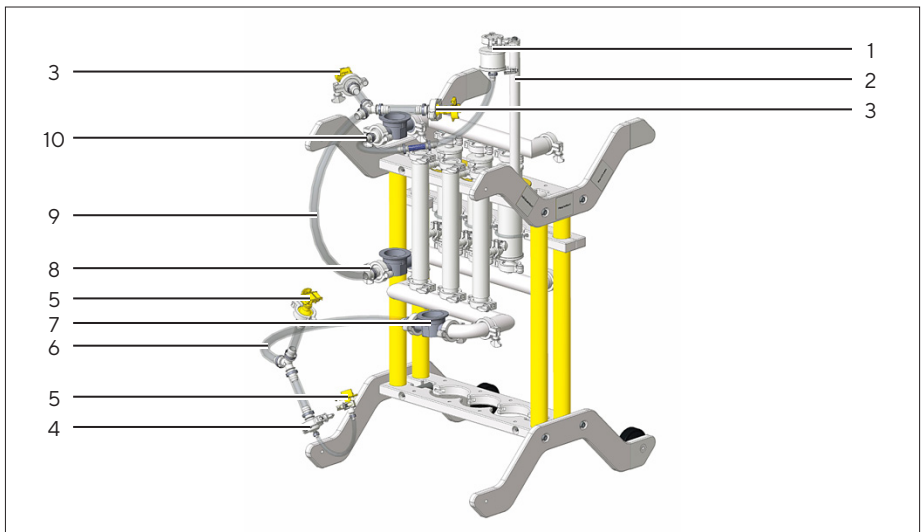
When the venting line valve (10) is closed increase to an inlet pressure of 2 bar | 29 psi. Flush for 10 min via the outlet (5) of the waste line. Alternative the Virosart® Max can be flushed at 1 bar | 14.5 psi inlet pressure for 20 min.

Observe the pressure at inlet: do **not** exceed 2.5 bar | 36 psi when filling through the Inlet (3). After following this procedure the Maxicaps® MR Virosart® Max is wetted completely.

6.4 Wetting & Equilibration for Maxicaps® MR Virosart® Media

1. For filling and proper wetting of the membrane use buffer | WFI | cell culture media. Follow instructions as described in chapter “6.1 Filling and Venting”.
2. When the venting line valve (10) is closed increase the inlet pressure to 0.4 – 0.6 bar | 5.8 – 8.7 psi. Flush for 2 min via the outlet (5) of the waste line.
3. Stop the media flow and drain the Maxicaps® MR Virosart® Media as described in chapter “7.2 Part II (optional): Emptying with Pressure After Filtration”, page 34 or open all valves (7, 8 and 10) to release media by gravity.
4. Fill and vent the Maxicaps® MR Virosart® Media as described in chapter “6.1 Filling and Venting”, page 29 with media suitable for Integrity testing.
 - ▶ Incomplete wetting might result in failed integrity testing. For proper wetting of the membrane prior to the pre-use integrity test, an IPA:WFI solution (v/v) (20:80) is required.
 - ▶ If the filtration is performed with media containing surface active agents (surface tension ≤ 60 mN/m), wetting with buffer | WFI | cell culture media for post-use-integrity test is sufficient.
 - ▶ If the filtration is performed with media in the absence of surface active agents (surface tension > 60 mN/m), wetting with IPA:WFI solution (v/v) (20:80) for post-use-integrity test is required.
5. When the venting line valve (10) is closed increase to an inlet pressure of 2.4 – 2.5 bar | 34.8 – 36.2 psi.
 - ▶ Flush Maxicaps® MR3 Virosart® Media for 30 min.
 - ▶ Flush Maxicaps® MR6 Virosart® Media for 40 min.
 - ▶ Observe the pressure at inlet: do **not** exceed 2.5 bar | 36 psi when filling through the Inlet (3).
 - ▶ After following this procedure the Maxicaps® MR Virosart® Media is wetted completely.

7 Filtration



7.1 Part I: Connection and Filtration

Perform filling and venting as described in the previous chapter. If no pre-use IT is needed and the system was not drained after wetting and flushing the chapter “6 Wetting & Equilibration”, page 29 can be skipped.

1. Make sure the venting line valve (10) is closed.
2. Connect the process line to the inlet (3).
3. Connect the collecting line to outlet (5). Make sure that the second outlet option not connected to the collecting line is closed with a tube clamp.
4. Open inlet valve (8).
5. Open outlet valve (7).
6. Start the filtration process.

If required, please perform integrity testing of the device, following the same instructions as for the pre-use integrity testing (see chapter “8.1 Integrity Testing”, page 37).

7.2 Part II (optional): Emptying with Pressure After Filtration

If not needed proceed to Part III – Disconnection.

Option A: Emptying using inlet line

1. Close the inlet valve (8) and venting line valve (10). Possibly not needed if other equipment (e.g. Maxicaps® MR Virosart® Max) is connected to the inlet side and the pressurized air supply is also connected to this equipment so that the emptying is performed at once for the complete equipment-chain.
2. Connect the supply of pressurized air to the inlet (3).
3. Open the inlet valve and apply a max. pressure of 0.5 bar | 7.2 psi.
4. Empty the system with pressurized air in the direction of the outlet of the device.
5. Stop the air supply after emptying, close the inlet valve (8) and outlet valve (7) and open venting line valve (10).
6. Wait until the pressure is released through the opened air filter (1).
7. Close the opened venting line valve (10), when the device is not under pressure anymore.

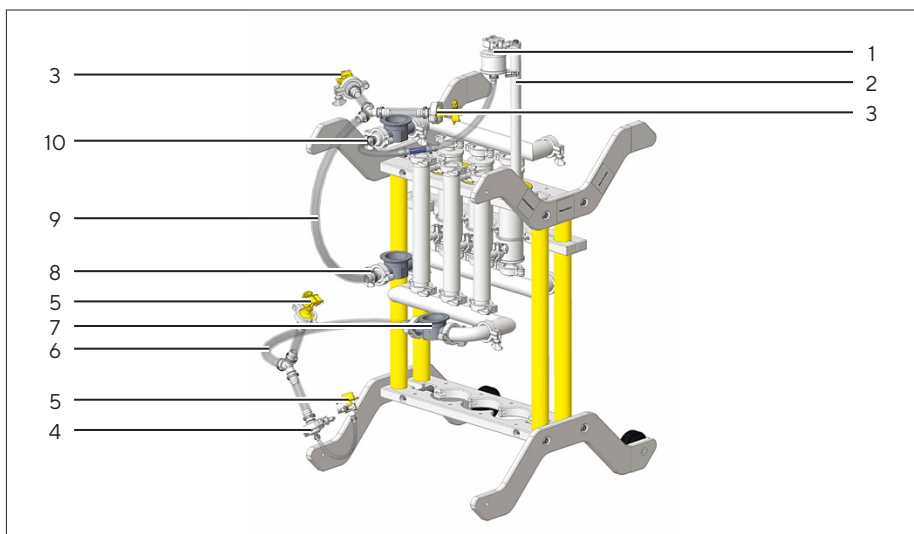
Option B: Emptying using the air filter.

1. Close the inlet valve (8).
2. Connect the pressurized air supply to the Tri-Clamp of the air filter (1).
3. Open venting line valve (10), apply max. pressure of 0.5 bar | 7.2 psi.
4. Empty the system with pressurized air in the direction of the outlet of the device.
5. Stop the air supply after emptying, close venting line valve (10) and outlet valve (7).
6. Disconnect the pressurized air supply.
7. Open the venting line valve (10).
8. Wait until the pressure lowers through the air filter.
9. Close the venting line valve (10).

7.3 Part III Disconnection

1. Make sure the device is not under pressure anymore.
2. Close inlet valve (8), venting line valve (10) and outlet valve (7).
3. Disconnect the supply lines from inlet (3).
4. Disconnect the receiving line from outlet (5).

8 Pre- & Post-Use Integrity Test



1. Prior to integrity testing make sure that the Maxicaps® MR Viosart® is vented and wetted thoroughly (e.g follow the flushing instructions in chapter 6 or make sure wetting was efficient due to filtration).
2. Drain the system prior to Integrity Testing as described in chapter “7.2 Part II (optional): Emptying with Pressure After Filtration”, page 34
3. Perform the test with Sartochek® as described in chapter “8.1 Integrity Testing”, page 37.

It is recommended to use a pressure indicator on Maxicaps® MR inlet side (e.g. Sartorius Sensor Transfer Set) for pressure control throughout all process steps. Further it is highly recommended to have a flow rate indicator at the inlet side. Prior to integrity testing close the inlet valve (8), outlet valve (7) and venting line valve (10).

4. Perform an integrity test only with an installed pressure safety device (see chapter "8.2 Pressure Safety Device", page 38). It is important to take the air filter off the air filter holder during the integrity test with Pressure Safety Device MR for safety reasons.

8.1 Integrity Testing

CAUTION

Use a safety pressure device when connected to pressurized gas (see chapter 10.1, page 44).

Risk of injury due to non-compliance with operating pressure conditions! Deviating from safety precautions may cause bursting of tubes or system components, injuring people.

- Wear appropriate personal protective equipment.
 - Do **not** exceed the maximum operating pressure.
 - Do **not** use gases other than air and nitrogen.
 - Do **not** perform on a dry Maxicaps® MR system.
-

Integrity test must be performed by diffusive forward flow test at given test pressure. Any test pressure above 2.5 bar | 36.2 psi exceeds the max. operating pressure of the Maxicaps® MR system.

1. Connect the Sartocheck® to the pressure safety device (26787---PS) which has to be connected to the air filter (1).
Note: Please take the air filter (1) off the air filter holder (2) for the test. The system must be drained already.
2. Open outlet valve (7) and venting valve (10). Close inlet valve (8).
Note: a **not** properly closed inlet valve (8) could allow a diffusive air stream.
Make sure the tube clamp is not installed on the outlet line.
3. Start the diffusion test program on the Sartocheck®; the outlet line remains open; the pressure is applied at the upstream side of the device; liquid might run out from the outlet (5). Wait until the test is over. Wait until venting is over.

4. Close venting line valve (10).
5. Close the outlet valve (7).
6. Disconnect the Sartocheck® from the air filter (1), respectively the pressure safety device.

8.2 Pressure Safety Device

When Maxicaps® MR Virosart® is used with gas, i.e. for integrity testing, the use of a protective measure to prevent excess pressure is needed. In accordance to Pressure Equipment Directive 2014/68, Sartorius provides a pressure safety device.

This device consists of a 1½" Sanitary T-union assembled with a burst disc protecting the Maxicaps® MR Virosart® from pressure exceeding the max. operating pressure of 2.5 bar | 36.2 psi plus safety tolerance of 0.5 bar | 7.2 psi. The exit connector for the burst disc line is a 1½" Sanitary | ¾" hose barb connector.

The burst disc is specifically designed for this connection only and must only be used with these connectors.

The pressure safety device has to be installed at the Sanitary connector of the air filter (1) of the Maxicaps® MR Virosart®.

Sartorius Order Code: 26787---PS

9 Disassembling

For post-use decontamination it might be appropriate to disassemble the Maxicaps® MR Virosart® stand. By taking of the stand, the filter system will still be closed, but the size of the filter assembly is significantly reduced. Thereby it fits better to common autoclaves.

For further disassembling Tri-Clamp connections have to be opened which probably releases remaining media.

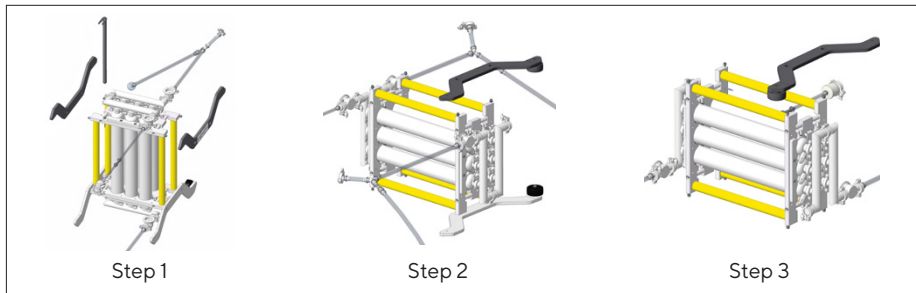
Please find the dimensions of the Maxicaps® MR Virosart® HF and Media versions without stand below.

		Maxicaps® MR2 & MR3	Maxicaps® MR4 & MR5 & MR6
Width	mm	630	630
Length	mm	403	685
Height	mm	873 mm	873 mm

Please find the dimensions of the Maxicaps® MR Virosart® Max versions without stand below.

		Maxicaps® MR3	Maxicaps® MR6	Maxicaps® MR9
Width	mm	630	630	630
Length	mm	179	320	461
Height	mm	1,000	1,000	1,000

Step by step disassembling (images below are representative for Maxicaps® MR Virosart®).



10 Technical Data

Please find the technical data of the Maxicaps® MR Virosart® HF and Media versions below.

		Maxicaps® MR2 & MR3	Maxicaps® MR4 & MR5 & MR6
Width	mm	672	672
Depth	mm	760	1041
Height	mm	1,050	1,050
Height with installed vent filter and holder	mm	1,375	1,375
Weight without packaging	kg	22	33
Weight of packaging	kg	10	11
Net volume of feed side, for integrity test	mL	1,800	3,300
Total volume	mL	12,000	18,000
Max. operation pressure with reinforced Si tubing	bar	2.5	2.5
Safety tolerance additional to max. operating pressure	bar	0.5	0.5
Recommended max. pressure for pressure safety protection for any use of pressurized gas (for use of gas, i.e. air or nitrogen)	bar	3.0	3.0

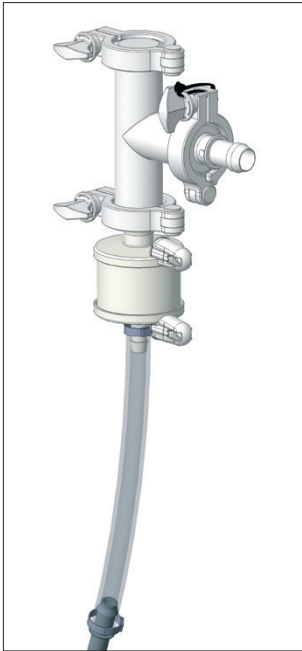
	Maxicaps® MR2 & MR3	Maxicaps® MR4 & MR5 & MR6
Sterilization, gamma compatible filter	gamma irradiation, delivered pre-sterilized, no re-sterilization	
Decontamination for disposal after use	Limited compatibility (valves & filters) for autoclave sterilization, sterilization acc. to evaluation & responsibility of user possible, no inline steaming	

Please find the technical data of the Maxicaps® MR Virosart® Max version below.

		Maxicaps® MR3	Maxicaps® MR6	Maxicaps® MR9
Width	mm	672	672	672
Depth	mm	760	912	1041
Height	mm	1,050	1,050	1,050
Height with installed vent filter and holder	mm	1,505	1,505	1,505
Weight without packaging	kg	23.8	34.7	45.1
Weight of packaging	kg	14.5	15.4	16.3
Net volume of feed side, for integrity test	mL	10,460	19,450	28,590
Total volume	mL	14,100	28,200	42,300
Max. operation pressure with reinforced Si tubing	bar	2.5	2.5	2.5
Safety tolerance additional to max. operating pressure	bar	0.5	0.5	0.5

		Maxicaps® MR3	Maxicaps® MR6	Maxicaps® MR9
Recommended max. pressure for pressure safety protection for any use of pressurized gas (for use of gas, i.e. air or nitrogen)	bar	3.0	3.0	3.0
Autoclave sterilization, autoclav. filter		Limited compatibility (valves) for autoclave sterilization, delivered non-sterile, sterilization acc. to evaluation & responsibility of user, no inline steaming		
Decontamination for disposal after use		Limited compatibility (valves) for autoclave sterilization, sterilization acc. to evaluation & responsibility of user possible, no inline steaming		

10.1 Pressure Safety Device MR



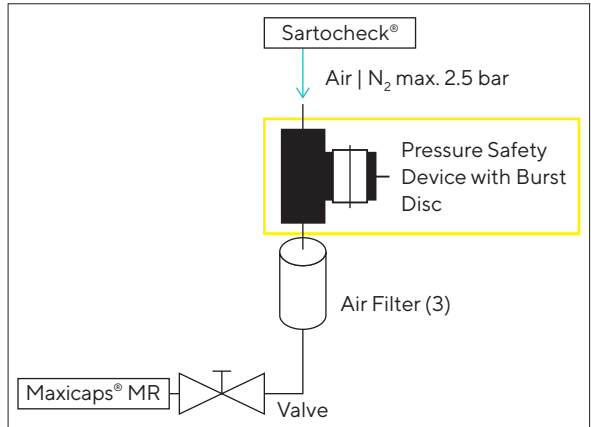
When Maxicaps® MR Virosart® is used with gas, i.e. for integrity testing, the use of a protective measure to prevent excess pressure is needed. In accordance to Pressure Equipment Directive 2014/68, Sartorius provides a pressure safety device.

This device consists of a 1½" Sanitary T-union assembled with a burst disc protecting the Maxicaps® MR Virosart® from pressure exceeding the max. operating pressure of 2.5 bar | 36.2 psi plus safety tolerance of 0.5 bar | 7.2 psi. The exit connector for the burst disc line is a 1½" Sanitary | ¾" hose barb connector.

The burst disc is specifically designed for this connection and must only be used with these connectors.

The pressure safety device has to be installed at the sanitary connector of the Air Filter (1) of the Maxicaps® MR Virosart®.

Sartorius Order Code: 26787---PS



11 Appendix

11.1 Applications Support

If required, please contact your Sartorius Stedim Biotech representative to obtain further information about technical data, product integrity testing or general information concerning specific applications.

Moreover our Validation Service and Technical Support units are always available to assist in questions of product and process validation, as well as training of staff and optimization of filtration processes.

11.2 Liability

Sartorius Stedim Biotech cannot assume liability if Maxicaps® MR Virosart® elements are subjected to improper use. In the interest of product development we reserve the right to make changes.

12 Conformity

12.1 EU Declaration of Conformity

The attached Declaration of Conformity hereby confirms compliance of the device with the directives cited.



Original

EU-Konformitätserklärung

EU Declaration of Conformity

Hersteller
 Manufacturer Sartorius Stedim Biotech GmbH
 37070 Goettingen, Germany

erklärt in alleiniger Verantwortung, dass das Betriebsmittel
 declares under sole responsibility that the equipment

Geräteart
 Device type **Filtrationsgerät für 3 oder 6 Filtercapsule**
Filtration device for 3 or 6 filter capsules

Single Use System aus 3 oder 6 verbundenen Filtercapsulen zur Filtration von Lösungen in der Herstellung von Pharmazeutika
 Single Use System of 3 or 6 connected filter capsules for the filtration of solutions in the manufacture of pharmaceuticals

Modell
 Model **MaxiCaps® MRx Virosart® Media** x = 3 oder/or 6

Ref. **3VI--28-IVG-MRx** x = 3 oder/or 6

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien – einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen – entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen – einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen – erfüllt:

in the form as delivered fulfils all the relevant provisions of the following European Directives – including any amendments valid at the time this declaration was signed – and meets the applicable requirements of the harmonized European Standards including any amendments valid at the time this declaration was signed – listed below:


2014/68/EU Druckgeräte / *Pressure Equipment*
 AD2000 Regelwerk / *Framework*
 DVS Richtlinie / *Regulation 2205-1*

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:

The person authorised to compile the technical file: Sartorius Lab Instruments GmbH & Co. KG
 Electronics & Product Compliance
 37070 Goettingen, Germany

Jahreszahl der CE-Kennzeichenvergabe / *Year of the CE mark assignment:* 19

Sartorius Stedim Biotech GmbH
 Goettingen, 2019-01-10


 Dr. Klaus-Jürgen Walter
 Head of BPS Quality


 Dr. Ralf Lausch
 Head of Product Development Separation



Original

EU-Konformitätserklärung EU Declaration of Conformity

Hersteller
Manufacturer Sartorius Stedim Biotech GmbH
37070 Goettingen, Germany

erklärt in alleiniger Verantwortung, dass das Betriebsmittel
declares under sole responsibility that the equipment

Geräteart
Device type **Filtrationsgerät für 2, 3, 4, 5 oder 6 Filtercapsule**
Filtration device for 2, 3, 4, 5 or 6 filter capsules

Single Use System aus 2, 3, 4, 5 oder 6 verbundenen Filtercapsulen zur Filtration von Lösungen in der Herstellung von Pharmazeutika
Single Use System of 2, 3, 4, 5 or 6 connected filter capsules for the filtration of solutions in the manufacture of pharmaceuticals

Modell
Model **MaxiCaps® MRx Virosart® HF** x = 2, 3, 4, 5 oder/or 6

Ref. **3VI--2B-MCG-MRx** x = 2, 3, 4, 5 oder/or 6

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Electronics & Product Compliance
37070 Goettingen, Germany

Jahreszahl der CE-Kennzeichenvergabe / *Year of the CE mark assignment:* **19**

Sartorius Stedim Biotech GmbH
Goettingen, 2019-01-10



Dr. Klaus-Jürgen Wätter
Head of BPS Quality



Dr. Ralf Lausch
Head of Product Development Separation



Original

EU-Konformitätserklärung
EU Declaration of Conformity

Hersteller Sartorius Stedim Biotech GmbH
 Manufacturer 37070 Goettingen, Germany

erklärt in alleiniger Verantwortung, dass das Betriebsmittel
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Geräteart Filtrationsgerät für 3, 6 oder 9 Filtercapsule
 Device type Filtration device for 3, 6 or 9 filter capsules

Single Use System aus 3, 6 oder 9 verbundenen Filtercapsulen zur Filtration von Lösungen in der Herstellung von Pharmazeutika
 Single Use System of 3, 6 or 9 connected filter capsules for the filtration of solutions in the manufacture of pharmaceuticals

Baureihe MaxiCaps® MR
 Type series

Modell 5uu73vvv3w-MRx | 5uu73vvv3wMMRx
 Model

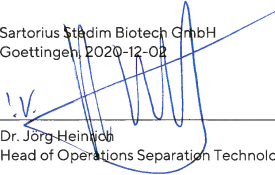
u = Nummer/number; v = Nummer oder Buchstabe / number or letter
 w = „G“, „C“ oder/or „-“ x = 3, 6 oder/or 9

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in the form as delivered fulfils all the relevant provisions of the following European Directive - including any amendments valid at the time this declaration was signed - and meets the applicable requirements of the framework/regulation listed below:

2014/68/EU Druckgeräte / Pressure Equipment
 AD2000 Regelwerk / Framework
 DVS Richtlinie / Regulation 2205-1

Sartorius Stedim Biotech GmbH
 Goettingen, 2020-12-02


 Dr. Jörg Heindl
 Head of Operations Separation Technologies


 Dr. Christian Hoffmann
 Manager of Product Compliance ST

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August-Spindler-Strasse 11
37079 Goettingen, Germany

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www.sartorius.com

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04 | 2024

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ML | DIR: 2552356-000-02

List of Sartorius material numbers applying to EPA-FIFRA

3V2--28-IVG-MR3

3V2--28-IVG-MR6

3VI--28-MCG-MR2

3VI--28-MCG-MR3

3VI--28-MCG-MR4

3VI--28-MCG-MR5

3VI--28-MCG-MR6

54A7358N3--MR3

54A7358N3--MR6

54A7358N3--MR9
