

IQ | OQ DOCUMENTATION

Vacuum Filtration Equipment

1-, 3-branch Combisart® Manifold

Type of vacuum filtration system

Biosart® 100 Monitor

Type of funnel

Fluid Vacuum Pump

Type of vacuum pump

INSTALLATION & OPERATIONAL QUALIFICATION DOCUMENTS

Vacuum Filtration Equipment

1-, 3-branch Combisart® Manifold

Type of vacuum filtration system

Biosart® 100 Monitor

Type of funnel

Fluid Vacuum Pump

Type of vacuum pump

INSTALLATION QUALIFICATION DOCUMENT

Vacuum Filtration Equipment

1-, 3-branch Combisart® Manifold

Type of vacuum filtration system

Biosart® 100 Monitor

Type of funnel

Fluid Vacuum Pump

Type of vacuum pump

Manifold Vacuum Filtration System
Biosart® 100 Monitors

IQ | OQ Documentation

IQ Protocol

**Installation Qualification
Content**

CLIENT INFORMATION

Client name: _____

Type of vacuum filtration system: **Manifold Combisart® System**

No. of filter stations: _____ (1 or 3)

Type of funnel: **Biosart® 100 Monitor**

1x Biosart® 100 Monitors Model no. and Lot no.: _____

1x Combisart® Manifold Model no. and Serial no.: _____

____ * x Combisart® Single Base
Model no.: _____

1x Vacuum Pump Model no. and Serial no.: _____

1x Vacuum Hose Model no.: _____

____ * x Biosart® Adapter Model no.: _____

*) for each filter station one single base and one adapter should be available

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

CONTENT OF INSTALLATION QUALIFICATION

- 1. Document Inspection
- 2. Physical Inspection
 - 2. A. Delivery Control
 - 2. B. Physical Aspects
 - 2. C. Power Management

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

Manifold Vacuum Filtration System
Biosart® 100 Monitors
IQ Protocol

IQ | OQ Documentation

Installation Qualification
1. Document Inspection

1. DOCUMENTS PROVIDED WITH THE VACUUM FILTRATION EQUIPMENT

Purpose: To ensure that all standard documentation has been supplied.

- A) User manual for Combisart® system including adapters and accessories: Yes No
- B) User manual for vacuum pump: Yes No

Operator Signature: _____ Date: _____

COMPANY: _____

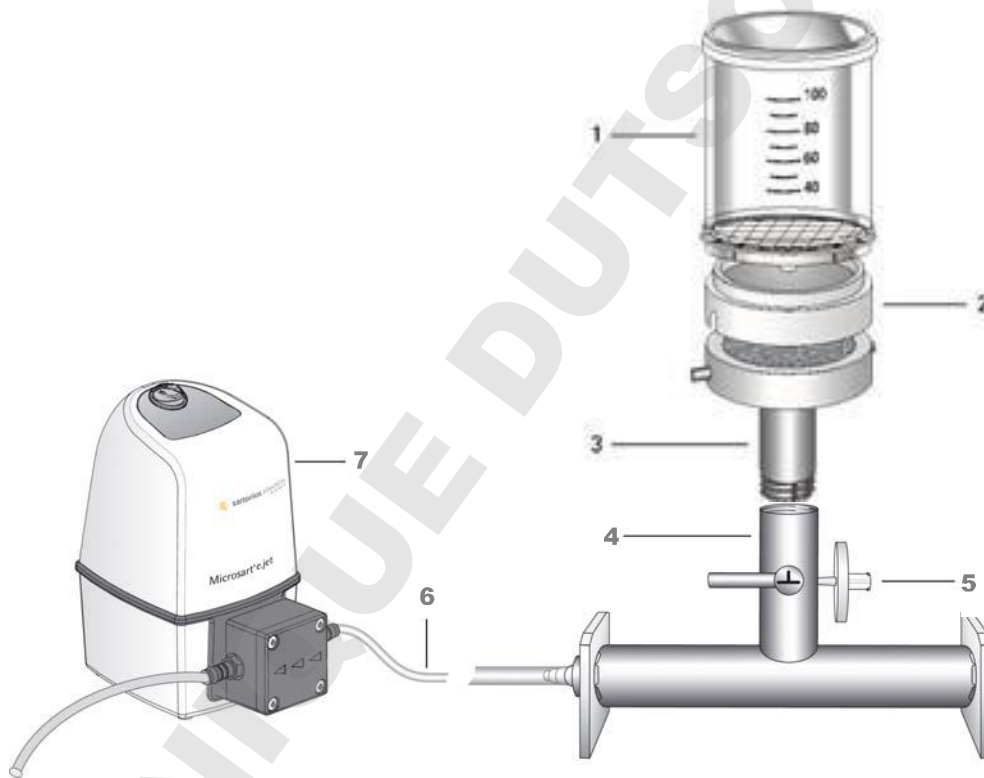
Witness Signature: _____ Date: _____

COMPANY: _____

2. A- DELIVERY CONTROL

Purpose: To ensure that all standard components have been supplied.

Set Up of a manifold filtration system with a Fluid Vacuum Pump



Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

IQ Protocol
**Installation Qualification
 2. Physical Inspection**
2. A- DELIVERY CONTROL

Purpose: To ensure that all standard components have been supplied.

A.[1] Biosart® 100 Monitors

- | | | | | |
|-----------------------|-----|--------------------------|----|--------------------------|
| 1. Packing carton: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Packaging foil: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Carton stickers: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 4. User manual: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 5. Certificate: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 6. Biosart® Monitors: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 7. Plugs: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 8. PE adapter: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

A.[2] Adapter(s) for Biosart® 100, units _____

- | | | | | |
|--------------------------|-----|--------------------------|----|--------------------------|
| 1. Biosart® 100 Adapter: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. PE-bag: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Sticker on PE-bag: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

A.[3] Combisart® Single Base(s), units _____

- | | | | | |
|----------------------------|-----|--------------------------|----|--------------------------|
| 1. Packing carton: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Packaging paper: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Carton stickers: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 4. Combisart® Single Base: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Operator Signature: _____

Date: _____

COMPANY: _____

Witness Signature: _____

Date: _____

COMPANY: _____

IQ Protocol
**Installation Qualification
 2. Physical Inspection**
2. A- DELIVERY CONTROL

Purpose: To ensure that all standard components have been supplied.

A.[4] Combisart® Manifold
A.[5] Minisart® SRP Venting Filter

- | | | | | |
|----------------------------------|-----|--------------------------|----|--------------------------|
| 1. Packing carton: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Foam inserts: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Carton stickers: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 4. User manual: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 5. Combisart® Individual Base: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 6. Minisart® SRP venting filter: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

A.[6] Vacuum Hose

- | | | | | |
|--------------------------|-----|--------------------------|----|--------------------------|
| 1. Vacuum hose tubing: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
|--------------------------|-----|--------------------------|----|--------------------------|

A.[7] Vacuum Pump

- | | | | | |
|-----------------------------|-----|--------------------------|----|--------------------------|
| 1. Packing carton: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Foam inserts: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Carton stickers: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 4. CE-conformity statement: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 5. User manual: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 6. Vacuum pump: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Operator Signature: _____

Date: _____

COMPANY: _____

Witness Signature: _____

Date: _____

COMPANY: _____

Manifold Vacuum Filtration System
Biosart® 100 Monitors
IQ Protocol

IQ | OQ Documentation

Installation Qualification
2. Physical Inspection

2. B- PHYSICAL ASPECTS

Purpose: To ensure that the equipment is supplied integer and undamaged.

- A) General appearance (no visible damage): Yes No
- B) Type plate | Serial numbers attached: Yes No
- C) CE – approval plate attached: Yes No
- D) Line cord installed: Yes No

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

Manifold Vacuum Filtration System
Biosart® 100 Monitors
IQ Protocol

IQ | OQ Documentation

Installation Qualification
2. Physical Inspection

2. C- VERIFICATION OF POWER MANAGEMENT

Purpose: To ensure that all electrical devices are suitable for the locally provided power supply.

C.1. Voltage Supply

Voltage locally _____ V

Suitability to local Voltage: Yes No

C.2. Frequency Supply

Frequency locally _____ Hz

Suitability to local Frequency: Yes No

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

Manifold Vacuum Filtration System
Biosart® 100 Monitors

IQ | OQ Documentation

IQ Protocol

**Installation Qualification
Summary**

PROTOCOL OF INSTALLATION QUALIFICATION

The following installation qualification protocols have been completed satisfactorily.

- Document Inspection
- Physical Inspection

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

OPERATIONAL QUALIFICATION DOCUMENT

Vacuum Filtration Equipment

1-, 3-branch Combisart® Manifold

Type of vacuum filtration system

Biosart® 100 Monitor

Type of funnel

Fluid Vacuum Pump

Type of vacuum pump

Manifold Vacuum Filtration System
Biosart® 100 Monitors

IQ | OQ Documentation

OQ Protocol

**Operational Qualification
Content**

CLIENT INFORMATION

Client name: _____

Type of vacuum filtration system: **Manifold Combisart® System**

No. of filter stations: _____ (1 or 3)

Type of funnel: **Biosart® 100 Monitor**

Serial | Lot numbers of the equipment

Biosart® 100 Monitor Lot no.: _____

Combisart® Manifold Serial no.: _____

Vacuum Pump Serial no.: _____

CONTENT OF OPERATIONAL QUALIFICATION

- I. Assembly of the System
- II. Start-Up and Functional Tests
 - A. Combisart® tap positions and their functions
 - B. Start-up the system
 - C. Verification of the Combisart® taps
- III. Test Filtration

Operator Signature: _____ Date: _____

COMPANY: _____

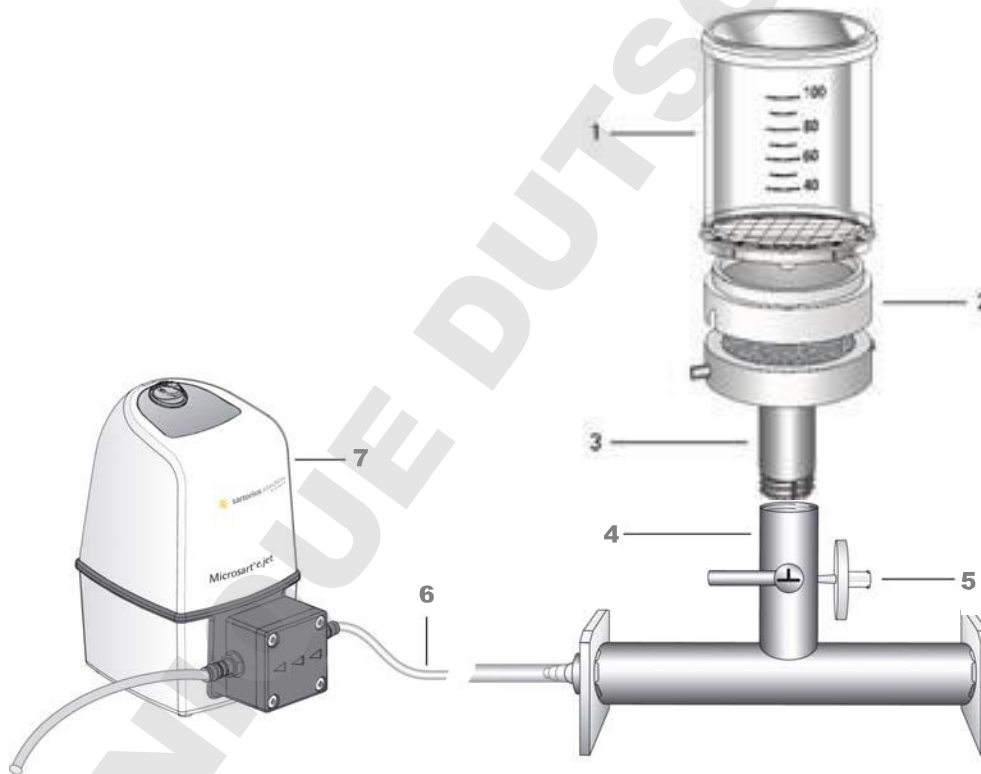
Witness Signature: _____ Date: _____

COMPANY: _____

I. ASSEMBLY OF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

Set Up of a manifold filtration system with a Fluid Vacuum Pump



Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

I. ASSEMBLY OF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

Remark: In the following section the assembly of the Combisart® System is described in detail. If your Combisart® System has more than one filter station, please make sure that you follow the instructions for every filter station.

1. Changing the positions of the hose nipple and the cap of the Combisart® manifold [4] by using a 24-mm open-end wrench (spanner).

The hose nipple is on the left side of the Combisart® manifold [4], when tap(s) are in front Yes No

The cap is on the right side of the Combisart® manifold [4], when tap(s) are in front Yes No

Firm fit of all parts Yes No

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

I. ASSEMBLY OF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

2. Screw the Combisart® single base [3] into the thread of the Combisart® manifold [4], turning the Combisart® single base [3] until the two pins are positioned either right | left or front | back.
 Tighten the threaded nut using a 24-mm open-end wrench (spanner).

Firm fit of the Combisart® single base Yes No

All Combisart® single bases fit Yes No

3. Insert the flat silicone gasket into the Combisart® single base [3], and place the stainless steel filter support (frit) onto the silicone gasket.

Gasket and frit are positioned Yes No

All gaskets and frits are positioned Yes No

Operator Signature: _____

Date: _____

COMPANY: _____

Witness Signature: _____

Date: _____

COMPANY: _____

I. ASSEMBLY OF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

4. Place the Biosart® 100 adapter [2] onto the
 Combisart® single base [3]

All Biosart® 100 adapters are placed Yes No

Firm fit of all components Yes No

5. Insert the air filter [5] into the venting hole

Venting hole closed with Minisart® SRP Yes No

All venting holes closed with Minisart® SRP Yes No

6. Cutting the vacuum hose [6] in half

Vacuum hose cut Yes No

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

I. ASSEMBLY OF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

7. Mounting one end of one half of the vacuum hose [6] on the hose nipple providing vacuum of the vacuum pump [7] (Microsart® e.jet: Right side) and the other end on the hose nipple of the Combisart® manifold [4].

Hose seated tight at both ends Yes No

8. Mounting the remaining vacuum hose [6] with one end on the outlet-hose nipple of the vacuum pump [7] and direct the other end to the drain.

All hose connections tight Yes No

9. Connecting the line cord

Firm connection of the cable Yes No

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

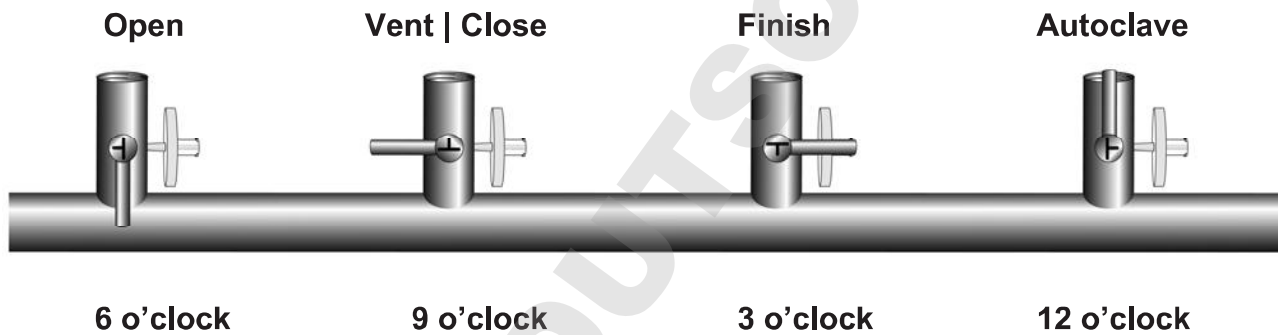
COMPANY: _____

Operational Qualification
II. Start-Up and Functional Test

II. A- COMBISART® TAP POSITIONS AND THEIR FUNCTIONS

Purpose: To ensure that the Combisart® tap is used correctly. So the vacuum below the membrane filter is released sterilely.

Tap Position:



Function:

For Filtration

The full vacuum draws the sample through the membrane filter. The venting filter is "off-line."

After Filtration

The vacuum between the tap and membrane filter is released under sterile conditions. Secondary contamination of the bottom of the filter is ruled out entirely.

After the Filtration Run

The residual vacuum between the pump and valve is released via the sterilizing grade filter.

For Autoclaving

For reliable sterilization, the steam flows freely through all openings.

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

II. B- START-UP THE SYSTEM

Purpose: To ensure that the Combisart® System is working correctly.

B.1. Start-Up the system

Turning each of the Combisart® taps to position “Vent | Close” (9 o’clock) and switching the vacuum pump on. If a Woulff’s bottle is used, making sure the tap is closed.

Place Biosart® 100 Monitor(s) [1] on top of the Biosart® 100 Adapter(s) [2].

- | | | | | |
|--|-----|--------------------------|----|--------------------------|
| 1. Pump running, audible noise | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Vacuum is build up in the system | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Biosart® 100 Monitor(s) are installed | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

II. C- VERIFICATION OF THE COMBISART® TAP

Purpose: To ensure that the Combisart® tap is working and used correctly. So the vacuum below the membrane filter is released sterilely.

Remark: In the following section the test of the functionality of the Combisart® 3-way-taps is described. If your Combisart® System has more than one filter station, please make sure that you follow the instructions for every Combisart® tap separately, while the other taps are closed (9 o'clock position).

C.1. Functionality Combisart® Tap Position "Open"

Place a Biosart® 100 Monitor [1] on top of the Biosart® 100 Adapter [2] and fill the Monitor with 100 ml tap water.

Turn the Combisart® tap to position "Open" (6 o'clock)

- | | | | | |
|--|-----|--------------------------|----|--------------------------|
| 1. Water is drawn through the Biosart® 100 Monitor | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. <u>No</u> vacuum occurs on the venting filter Minisart® SRP | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. <u>All</u> Combisart® taps were tested | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Operator Signature: _____

Date: _____

COMPANY: _____

Witness Signature: _____

Date: _____

COMPANY: _____

OQ Protocol
**Operational Qualification
 II. Start-Up and Functional Test**
II. C- VERIFICATION OF THE COMBISART® TAP

Purpose: To ensure that the Combisart® tap is working and used correctly. So the vacuum below the membrane filter is released sterily.

C.2. Functionality Combisart® Tap Position “Vent | Close”

Turn the Combisart® tap to position “Vent | Close” (9 o’clock). Refill the Biosart® 100 Monitor with tap water.

- | | | | | |
|--|-----|--------------------------|----|--------------------------|
| 1. Vacuum occurs on the venting filter Minisart® SRP | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. <u>No</u> water is drawn through the Biosart® 100 Monitor | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. <u>All</u> Combisart® taps were tested | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

C.3. Functionality Combisart® Tap Position “Finish”

The Biosart® 100 Monitor is filled with tap water. Turn the Combisart® tap to position “Finish” (3 o’clock)

- | | | | | |
|--|-----|--------------------------|----|--------------------------|
| 1. Vacuum occurs on the venting filter Minisart® SRP | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. <u>No</u> water is drawn through the Biosart® 100 Monitor | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. The vacuum of the system is released | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 4. <u>All</u> Combisart® taps were tested | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

2. C- VERIFICATION OF THE COMBISART® TAP

Purpose: To ensure that the Combisart® tap is working and used correctly.
 So the vacuum below the membrane filter is released sterilely.

C.4. Functionality Combisart® Tap Position “Autoclave”

The Biosart® 100 Monitor is filled with tap water. Turn the Combisart® tap to position “Autoclave” (12 o’clock)

- | | | |
|--|------------------------------|-----------------------------|
| 1. Water is drawn through the Biosart® 100 Monitor | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. Vacuum occurs on the venting filter Minisart® SRP | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. <u>All</u> Combisart® taps were tested | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

III. VERIFICATION OF THE FUNCTION – TEST FILTRATION

Purpose: To ensure that the Combisart® System is working correctly.

1. Placing Biosart® 100 Monitor(s) [1] on top of each of the Biosart® 100 Adapters [2] and turning the Combisart® tap(s) to position “Vent | Close” (9 o’clock). Switching on the vacuum pump [9] (the tap of the Woulff’s bottle must be closed).

- | | | | | |
|-------------------------------------|-----|--------------------------|----|--------------------------|
| 1. Pump running, audible noise | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Vacuum is build up in the system | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

2. Filling the Biosart® 100 Monitor with 100 ml of tap water and turning the Combisart® tap to position “Open” (6 o’clock)

- | | | | | |
|---|-----|--------------------------|----|--------------------------|
| 1. Filling procedure functioning | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Emptying procedure functioning | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. <u>All</u> Combisart® taps were tested | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____

III. VERIFICATION OF THE FUNCTION – TEST FILTRATION

Purpose: To ensure that the Combisart® System is working correctly.

3. After the filtration turning the Combisart® tap to position “Vent | Close” (9 o’clock). The vacuum between the tap and Biosart® 100 Monitor is released under sterile conditions by the Minisart® SRP.

- | | | |
|---|------------------------------|-----------------------------|
| 1. Vacuum occurs on the venting filter Minisart® SRP for a short moment | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. Noiseless removing of the Biosart® 100 Monitor | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. <u>All</u> Combisart® taps were tested | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Operator Signature: _____

Date: _____

COMPANY: _____

Witness Signature: _____

Date: _____

COMPANY: _____

Manifold Vacuum Filtration System
Biosart® 100 Monitors

IQ | OQ Documentation

OQ Protocol

**Operational Qualification
Summary**

PROTOCOL OF OPERATIONAL QUALIFICATION

The following operational qualification protocols had been completed satisfactorily.

- Assembly
- Start-Up and Functional Tests
- Test Filtration

Operator Signature: _____ Date: _____

COMPANY: _____

Witness Signature: _____ Date: _____

COMPANY: _____