

## **IQ | OQ DOCUMENTATION**

### **Vacuum Filtration Equipment**

#### **1-, 3-, 6-branch Combisart® Manifold**

Type of vacuum filtration system

#### **Biosart® 100 Monitor**

Type of funnel

#### **Suction Flask 5-Liters**

Type of suction flask

#### **Electrical Membrane Pump**

Type of vacuum pump

# INSTALLATION & OPERATIONAL QUALIFICATION DOCUMENTS

## Vacuum Filtration Equipment

### 1-, 3-, 6-branch Combisart® Manifold

Type of vacuum filtration system

### Biosart® 100 Monitor

Type of funnel

### Suction Flask 5-Liters

Type of suction flask

### Electrical Membrane Pump

Type of vacuum pump

# INSTALLATION QUALIFICATION DOCUMENT

## Vacuum Filtration Equipment

### 1-, 3-, 6-branch Combisart® Manifold

Type of vacuum filtration system

### Biosart® 100 Monitor

Type of funnel

### Suction Flask 5-Liters

Type of suction flask

### Electrical Membrane Pump

Type of vacuum pump

**CLIENT INFORMATION**

Client name: \_\_\_\_\_

Type of vacuum filtration system: **Manifold Combisart® System**  
 No. of filter stations: \_\_\_\_\_ **(1, 3 or 6)**  
 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.: \_\_\_\_\_

**1x Suction Flask** Model no.: \_\_\_\_\_

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

**Choice one out of two water traps** (please delete where inapplicable)

**1x Vacusart®** Model no. and Lot no.: \_\_\_\_\_

**1x Woulff's bottle** Model no.: \_\_\_\_\_

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: \_\_\_\_\_

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Manifold Vacuum Filtration System  
Biosart® 100 Monitors  
**IQ Protocol**

IQ | OQ Documentation

**Installation Qualification**  
**1. Document Inspection**

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**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: \_\_\_\_\_

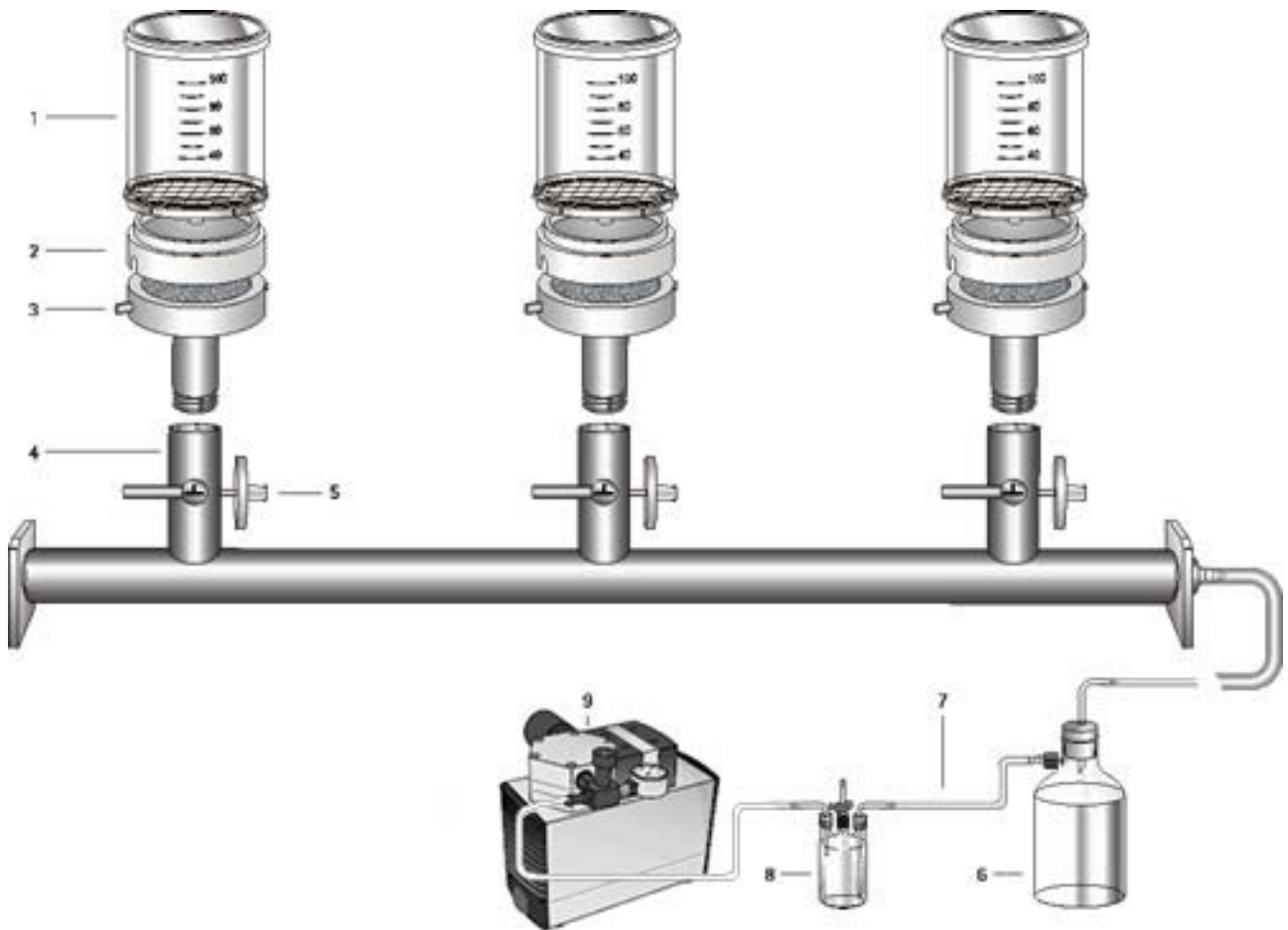
COMPANY: \_\_\_\_\_

**Installation Qualification**  
**2. Physical Inspection**

**2. A- DELIVERY CONTROL**

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

**Set Up of a manifold filtration system with a 5-liter suction flask**



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: \_\_\_\_\_



Manifold Vacuum Filtration System  
 Biosart® 100 Monitors

IQ | OQ Documentation

**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] 5-Liters Suction Flask | Vacuum Bottle**

- |                                   |     |                          |    |                          |
|-----------------------------------|-----|--------------------------|----|--------------------------|
| 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. Suction Flask   Vacuum Bottle: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 5. Hose nipple:                   | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 6. Glass tube:                    | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 7. Stopper:                       | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

**A.[7] Vacuum Hose**

- |                          |     |                          |    |                          |
|--------------------------|-----|--------------------------|----|--------------------------|
| 1. Vacuum hose   tubing: | 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.[8] Choice one out of two Water Traps** (please delete where inapplicable)

 **Vacusart®**

- |                           |     |                          |    |                          |
|---------------------------|-----|--------------------------|----|--------------------------|
| 1. Packaging carton:      | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Carton stickers:       | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. PE-bag:                | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 4. Sticker on PE-bag:     | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 5. Vacusart® Filter Unit: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

 **Woulff's Bottle**

- |                         |     |                          |    |                          |
|-------------------------|-----|--------------------------|----|--------------------------|
| 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. Woulff's Bottle:     | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 5. Glass tube, long:    | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 6. Glass tube, short:   | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 7. Glass tube with tap: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 8. Caps:                | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Operator Signature: \_\_\_\_\_

Date: \_\_\_\_\_

COMPANY: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Date: \_\_\_\_\_

COMPANY: \_\_\_\_\_

**2. A- DELIVERY CONTROL**

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

**A.[9] 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: \_\_\_\_\_

**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: \_\_\_\_\_

## 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: \_\_\_\_\_

## PROTOCOL OF INSTALLATION QUALIFICATION

The following installation qualification protocols had been completed satisfactorily.

- Document Inspection
- Physical Inspection

Operator Signature: \_\_\_\_\_ Date: \_\_\_\_\_

COMPANY: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

COMPANY: \_\_\_\_\_

# OPERATIONAL QUALIFICATION DOCUMENT

## Vacuum Filtration Equipment

### 1-, 3-, 6-branch Combisart® Manifold

Type of vacuum filtration system

### Biosart® 100 Monitor

Type of funnel

### Suction Flask 5-Liters

Type of suction flask

### Electrical Membrane Pump

Type of vacuum pump

Manifold Vacuum Filtration System  
Biosart® 100 Monitors

IQ | OQ Documentation

**OQ Protocol**

**Operational Qualification  
Content**

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## CLIENT INFORMATION

Client name: \_\_\_\_\_

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

**No. of filter stations:**                      \_\_\_\_\_ **(1, 3 or 6)**

**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.: \_\_\_\_\_

**Vacusart®** Lot no.: \_\_\_\_\_

(please delete where inapplicable)

## 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: \_\_\_\_\_

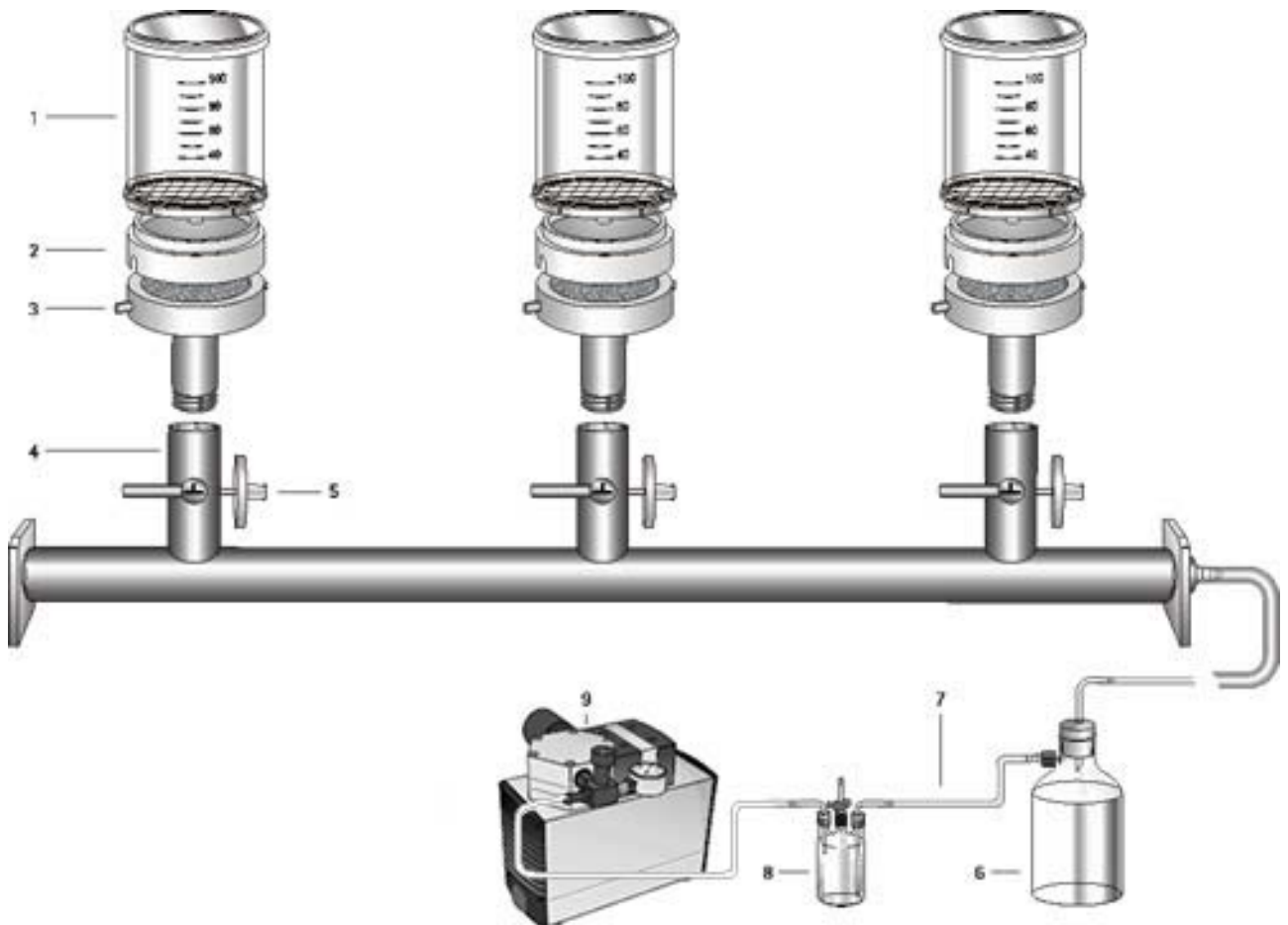
COMPANY: \_\_\_\_\_



**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 5-liter suction flask**



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. 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

2. 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

3. 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

4. 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

5. Insert the glass tube into the silicone  
 stopper and insert the stopper into the  
 opening of the suction flask [6].

Firm fit of the stopper and the tube connector 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**6. Screwing the hose nipple on the outlet of the suction flask [6]**

Firm fit of the hose nipple

Yes  No **7. Cutting the vacuum hose [7] in half**

Vacuum hose cut

Yes  No **8. Mounting one end of one half of the vacuum hose [7] on the glass tube and the other end on the hose nipple of the Combisart® manifold [4].**

Hose seated tight at both ends

Yes  No **9. Cutting the remaining vacuum hose [7] in half**

Hose cut

Yes  No 

Operator Signature: \_\_\_\_\_

Date: \_\_\_\_\_

COMPANY: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Date: \_\_\_\_\_

COMPANY: \_\_\_\_\_

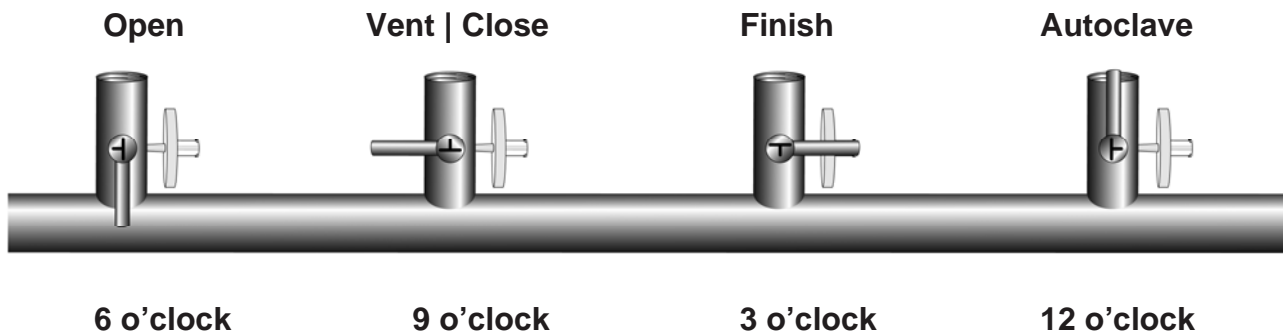


**Operational Qualification**  
**II. Start-Up and Functional Test**

**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: \_\_\_\_\_



**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.

**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<br>Minisart® SRP         | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. <u>No</u> water is drawn through the Biosart® 100<br>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<br>Minisart® SRP         | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. <u>No</u> water is drawn through the Biosart® 100<br>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  No
- 2. Vacuum is build up in the system Yes  No

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  No
- 2. Emptying procedure functioning Yes  No
- 3. All Combisart® taps were tested Yes  No

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<br>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: \_\_\_\_\_

**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: \_\_\_\_\_