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
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Type of funnel

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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: _______________________________________________________________________________________

Page 5 of 29
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 ☐
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**
## 2. A- DELIVERY CONTROL

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

### A.[1] Biosart® 100 Monitors

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Packing carton:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Packaging foil:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Carton stickers:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. User manual:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Certificate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Biosart® Monitors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Plugs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. PE adapter:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Biosart® 100 Adapter:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. PE-bag:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Sticker on PE-bag:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Packing carton:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Packaging paper:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Carton stickers:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Combisart® Single Base:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Operator Signature:_______________________ Date:________________

COMPANY: __________________________________________________________________________

Witness Signature:_______________________ Date:________________

COMPANY: __________________________________________________________________________
2. A- DELIVERY CONTROL

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


1. Packing carton: Yes □ No □
2. Foam inserts: Yes □ No □
3. Carton stickers: Yes □ No □
4. User manual: Yes □ No □
5. Combisart® Individual Base: Yes □ No □
6. Minisart® SRP venting filter: Yes □ No □


1. Packing carton: Yes □ No □
2. Foam inserts: Yes □ No □
3. Carton stickers: Yes □ No □
4. Suction Flask | Vacuum Bottle: Yes □ No □
5. Hose nipple: Yes □ No □
6. Glass tube: Yes □ No □
7. Stopper: Yes □ No □

A.[7] Vacuum Hose

1. Vacuum hose | tubing: Yes □ No □

Operator Signature:_________________________ Date:__________

COMPANY: ____________________________________________

Witness Signature:_________________________ Date:__________

COMPANY: ____________________________________________
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: 
  2. Carton stickers: 
  3. PE-bag: 
  4. Sticker on PE-bag: 
  5. Vacusart® Filter Unit: 

☐ Woulff’s Bottle
  1. Packing carton: 
  2. Foam inserts: 
  3. Carton stickers: 
  4. Woulff’s Bottle: 
  5. Glass tube, long: 
  6. Glass tube, short: 
  7. Glass tube with tap: 
  8. Caps: 

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 □ No □
2. Foam inserts: Yes □ No □
3. Carton stickers: Yes □ No □
4. CE-conformity statement: Yes □ No □
5. User manual: Yes □ No □
6. Vacuum pump: Yes □ No □
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 ☐
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
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

   
   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: ___________________________________________________________________
I. ASSEMBLY OF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

10. Mounting one end of one half of the vacuum hose [7] on the hose nipple of the suction flask [6] and the other end on the inlet-hose nipple of the water trap [8]. The inlet of the Woulff's bottle is the long glass tube.

Hose seated tight at both ends

Yes ☐ No ☐

11. Mounting the remaining vacuum hose [7] with one end on the outlet-hose nipple of the water trap [8] (short glass tube of the Woulff's bottle) and with the other end on the hose nipple providing vacuum of the vacuum pump [9].

All hose connections tight

Yes ☐ No ☐

12. Connecting the line cord

Firm connection of the cable

Yes ☐ No ☐

Operator Signature: ___________________________ Date: ________________

COMPANY: ________________________________________________________________________________

Witness Signature: ___________________________ Date: ________________

COMPANY: ________________________________________________________________________________
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 steriley.

**Tap Position:**

- **Open**
- **Vent | Close**
- **Finish**
- **Autoclave**

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

1. Pump running, audible noise
   - Yes □  No □

2. Vacuum is build up in the system
   - Yes □  No □

3. CombiSart® 100 Monitor(s) are installed
   - Yes □  No □

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 steriley.

**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 ☐  No ☐

2. No vacuum occurs on the venting filter Minisart® SRP
   - Yes ☐  No ☐

3. All Combisart® taps were tested
   - Yes ☐  No ☐
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 Minisart® SRP
   - Yes □  No □
2. **No** water is drawn through the Biosart® 100 Monitor
   - Yes □  No □
3. **All** Combisart® taps were tested
   - Yes □  No □

### 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 □  No □
2. **No** water is drawn through the Biosart® 100 Monitor
   - Yes □  No □
3. The vacuum of the system is released
   - Yes □  No □
4. **All** Combisart® taps were tested
   - Yes □  No □

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 steriley.

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 ☐ No ☐

2. Vacuum occurs on the venting filter Minisart® SRP
   - Yes ☐ No ☐

3. All Combisart® taps were tested
   - Yes ☐ No ☐
### 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 Minisart® SRP for a short moment   Yes [ ] No [ ]

2. Noiseless removing of the Biosart® 100 Monitor   Yes [ ] No [ ]

3. All Combisart® taps were tested   Yes [ ] No [ ]
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:  ______________________________________________________________________