Vacuum Filtration Equipment

**Individual CombiSart® System**
Type of vacuum filtration system

**Biosart®100 Monitor**
Type of funnel

**Suction Flask 1- | 2-Liters**
Type of suction flask

**Electrical Membrane Pump**
Type of vacuum pump
INSTALLATION & OPERATIONAL QUALIFICATION DOCUMENTS

Vacuum Filtration Equipment

Individual Combisart® System
Type of vacuum filtration system

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Type of funnel

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INSTALLATION QUALIFICATION DOCUMENT

Vacuum Filtration Equipment

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Type of vacuum filtration system

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Type of funnel

**Suction Flask 1- | 2-Liters**
Type of suction flask

**Electrical Membrane Pump**
Type of vacuum pump
## CLIENT INFORMATION

Client name: 

Type of vacuum filtration system: Individual CombiSart® System

No. of filter stations: 1

Type of funnel: Biosart®100 Monitor

### Equipment List

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

1x CombiSart® Individual Base  
Model no. and Serial no.: 

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

1x Vacuum Hose  
Model no.: 

1x Biosart® Adapter  
Model no.: 

1x Suction Flask  
Model no.: 

1x Silicone Stopper  
Model no.: 

### Water Traps

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: ____________________________________________
1. DOCUMENTS PROVIDED WITH THE VACUUM FILTRATION EQUIPMENT

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

A) User manual for Combiart® 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 an individual filtration system on top of a suction flask**
2. A- DELIVERY CONTROL

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

### A.[1] Biosart® 100 Monitors
1. Packing carton: Yes □ No □
2. Packaging foil: Yes □ No □
3. Carton stickers: Yes □ No □
4. User manual: Yes □ No □
5. Certificate: Yes □ No □
6. Biosart® Monitors: Yes □ No □
7. Plugs: Yes □ No □
8. PE adapter: Yes □ No □

### A.[2] Adapter for Biosart® 100
1. Biosart® 100 Adapter: Yes □ No □
2. PE-bag: Yes □ No □
3. Sticker on PE-bag: Yes □ No □

### A.[3] Combisart® Individual Base

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 □

Operator Signature:_________________________ Date:______________

COMPANY: ______________________________________________________________________

Witness Signature:_________________________ Date: ______________

COMPANY: ______________________________________________________________________
## 2. A- DELIVERY CONTROL

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

### A.[5] Silicone Stopper

<table>
<thead>
<tr>
<th>Component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicone stopper</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>PE-bag</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Sticker on PE-bag</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

### A.[6] Choice one out of two Suction Flasks (please delete where inapplicable)

- **2-Liters Suction Flask | Vacuum Bottle**
<table>
<thead>
<tr>
<th>Component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing carton</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Foam inserts</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Carton stickers</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Suction Flask</td>
<td>Vacuum Bottle:</td>
<td>☐</td>
</tr>
<tr>
<td>Hose nipple</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

- **1-Liter Suction Flask | Vacuum Bottle**
<table>
<thead>
<tr>
<th>Component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing carton</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Foam inserts</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Carton stickers</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Suction Flask</td>
<td>Vacuum Bottle:</td>
<td>☐</td>
</tr>
</tbody>
</table>

### A.[7] Vacuum Hose

<table>
<thead>
<tr>
<th>Component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacuum hose</td>
<td>tubing:</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.

**A.[8] Choice one out of two Water Traps** (please delete where inapplicable)

<table>
<thead>
<tr>
<th>Component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vacusart®</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Packaging carton:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Carton stickers:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. PE-bag:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Sticker on PE-bag:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Vacusart® Filter Unit:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Woulff’s Bottle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Packing carton:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Foam inserts:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Carton stickers:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Woulff’s Bottle:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Glass tube, long:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Glass tube, short:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Glass tube with tap:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Caps:</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.

**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: \[ \text{___________ V} \]

Suitability to local Voltage: Yes [ ] No [ ]

**C.2. Frequency Supply**

Frequency locally: \[ \text{___________ Hz} \]

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

**Individual Combisart® System**
Type of vacuum filtration system

**Biosart® 100 Monitor**
Type of funnel

**Suction Flask 1- | 2-Liters**
Type of suction flask

**Electrical Membrane Pump**
Type of vacuum pump
CLIENT INFORMATION

Client name:__________________________________________

Type of vacuum filtration system: Individual Combisart® System
No. of filter stations: 1
Type of funnel: Biosart® 100 Monitor

Serial | Lot numbers of the equipment

Biosart® 100 Monitor Lot no.:______________________________

Combisart® Individual Base 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 an individual filtration system on top of a suction flask.
I. ASSEMBLY OF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

1. Insert the Combisart® individual base [3] into the silicone stopper [5] and insert the stopper into the opening of the suction flask [6]. Insert the flat silicone gasket into the Combisart® individual base [3], and place the stainless steel filter support (frit) onto the silicone gasket.

   Level position of the individual base
   Yes ☐ No ☐

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

   Firm fit of all components
   Yes ☐ No ☐

3. Insert the air filter [4] into the venting hole

   Venting hole closed with Minisart® SRP
   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. Screwing the hose nipple on the outlet of the suction flask [6] (not necessary for 1-Liter flask)
   Firm fit of the hose nipple
   Yes □  No □

5. Cutting the vacuum hose [7] in half
   Hose cut
   Yes □  No □

6. 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 □

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 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 ✗

8. Connecting the line cord

   Firm connection of the cable  Yes ✗ No ✗
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 the Combisart® tap 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 a Biosart® 100 Monitor [1] on top of the Biosart® 100 Adapter [2].

1. Pump running, audible noise   Yes ☐ No ☐
2. Vacuum is build up in the system Yes ☐ No ☐
3. Biosart® 100 Monitor is 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 sterilely.

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)

<table>
<thead>
<tr>
<th></th>
<th>Water is drawn through the Biosart® 100 Monitor</th>
<th>Yes ☐ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>No vacuum occurs on the venting filter Minisart® SRP</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th></th>
<th>Vacuum occurs on the venting filter Minisart® SRP</th>
<th>Yes ☐ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>No water is drawn through the Biosart® 100 Monitor</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>

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.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 ☐

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 ☐

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. 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 ☐
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 ☐

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: _____________________________________________________