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 1- | 2-Liters
Type of suction flask

Electrical Membrane Pump
Type of vacuum pump

INSTALLATION & OPERATIONAL QUALIFICATION DOCUMENTS

Vacuum Filtration Equipment

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INSTALLATION QUALIFICATION DOCUMENT

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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.:_____

1x Silicone Stopper Model no.:_____

1x Tube Connector 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

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 Combisart® system including adapters and accessories: Yes ☐ No ☐

B) User manual for vacuum pump: Yes ☐ No ☐

Operator Signature:_____ Date:_____

COMPANY: _____

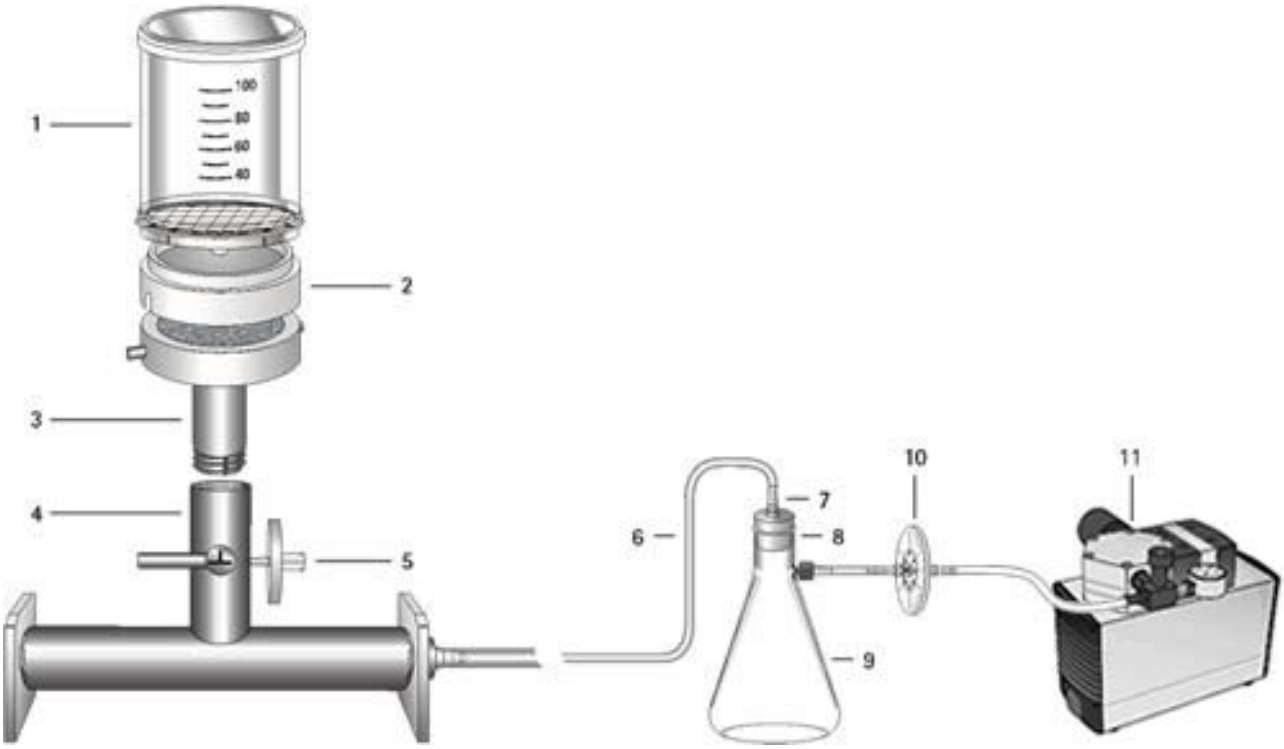
Witness Signature:_____ Date: _____

COMPANY: _____

2. A- DELIVERY CONTROL

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

Set Up of a manifold filtration system with a 1-|2-liter suction flask



Operator Signature:_____ Date:_____

COMPANY: _____

Witness Signature:_____ Date: _____

COMPANY: _____

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(s) for Biosart® 100, units____

1.	Biosart® 100 Adapter:	Yes ☐	No	☐
2.	PE-bag:	Yes ☐	No	☐
3.	Sticker on PE-bag:	Yes ☐	No	☐

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

1.	Packing carton:	Yes ☐	No	☐
2.	Packaging paper:	Yes ☐	No	☐
3.	Carton stickers:	Yes ☐	No	☐
4.	Combisart® Single Base:	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.[4] Combisart® Manifold
A.[5] Minisart® SRP Venting Filter

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 ☐

A.[6] Tube Connector

1.	Tube connector:	Yes ☐	No ☐
2.	PE-bag:	Yes ☐	No ☐
3.	Sticker on PE-bag:	Yes ☐	No ☐

A.[7] Vacuum Hose

1.	Vacuum hose | tubing:	Yes ☐	No ☐

A.[8] Silicone Stopper

1.	Silicone stopper:	Yes ☐	No ☐
2.	PE-bag:	Yes ☐	No ☐
3.	Sticker on PE-bag:	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.[9] Choice one out of two Suction Flasks (please delete where inapplicable)

☐ **2-Liters Suction Flask | Vacuum Bottle**

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	☐

☐ **1-Liter Suction Flask | Vacuum Bottle**

4.	Packing carton:	Yes ☐	No	☐
5.	Foam inserts:	Yes ☐	No	☐
6.	Carton stickers:	Yes ☐	No	☐
7.	Suction Flask | Vacuum Bottle:	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.[10] Choice one out of two Water Traps (please delete where inapplicable)

☐ **Vacusart®**

1. Packaging carton:	Yes ☐	No ☐
2. Carton stickers:	Yes ☐	No ☐
3. PE-bag:	Yes ☐	No ☐
4. Sticker on PE-bag:	Yes ☐	No ☐
5. Vacusart® Filter Unit:	Yes ☐	No ☐

☐ **Woulff's Bottle**

1. Packing carton:	Yes ☐	No ☐
2. Foam inserts:	Yes ☐	No ☐
3. Carton stickers:	Yes ☐	No ☐
4. Woulff's Bottle:	Yes ☐	No ☐
5. Glass tube, long:	Yes ☐	No ☐
6. Glass tube, short:	Yes ☐	No ☐
7. Glass tube with tap:	Yes ☐	No ☐
8. Caps:	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.[11] 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	☐

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 hade 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 1- | 2-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: _____

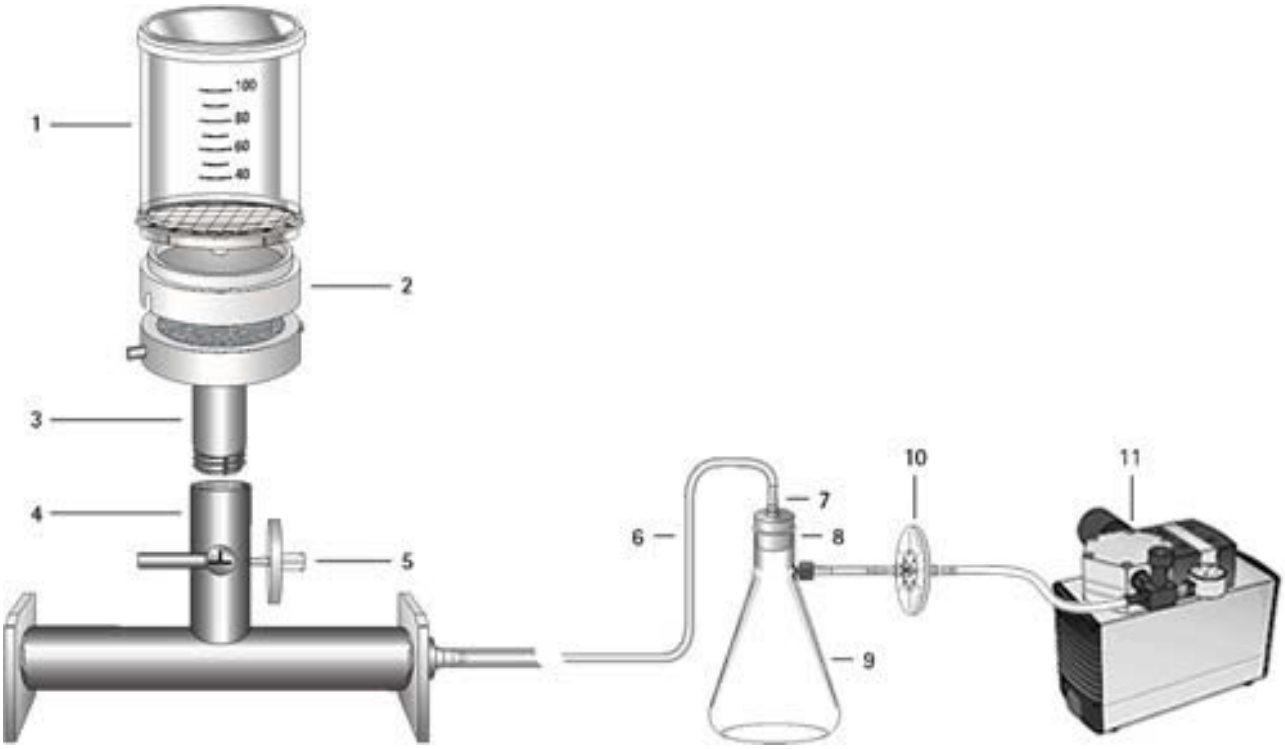
Witness Signature:_____ Date: _____

COMPANY: _____

I. ASSEMBLYOF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

Set Up of a manifold filtration system with a 1-|2-liter suction flask



Operator Signature:_____ Date:_____

COMPANY: _____

Witness Signature:_____ Date: _____

COMPANY: _____

I. ASSEMBLYOF 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 tube connector [7] into the silicone stopper [8] and insert the stopper into the opening of the suction flask [9].

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 [9] (not necessary for 1-Liter flask)

   Firm fit of the hose nipple Yes ☐ No ☐

7. Cutting the vacuum hose [6] in half

   Vacuum hose cut Yes ☐ No ☐

8. Mounting one end of one half of the vacuum hose [6] on the tube connector [7] 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 [6] 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 [6] on the hose nipple of the suction flask [9] and the other end on the inlet-hose nipple of the water trap [10]. 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 [6] with one end on the outlet-hose nipple of the water trap [10] (short glass tube of the Woulff's bottle) and with the other end on the hose nipple providing vacuum of the vacuum pump [11].

    All hose connections tight Yes ☐ No ☐

12. Connecting the line cord

    Firm connection of the cable Yes ☐ No ☐

Operator Signature:_____ Date:_____

COMPANY: _____

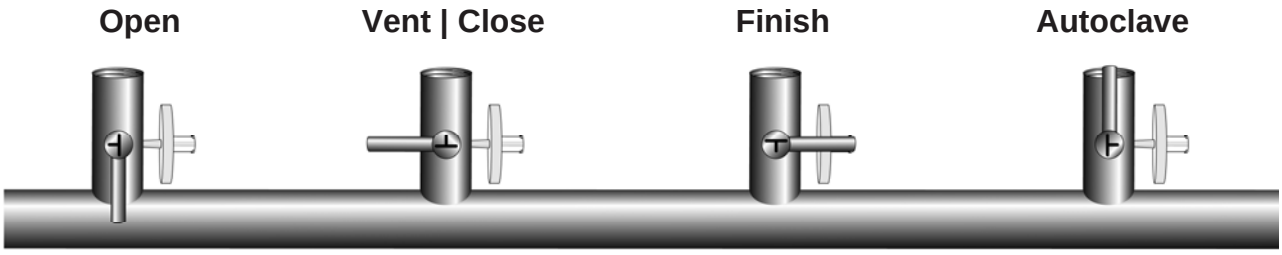
Witness Signature:_____ Date: _____

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 sterilely.

Tap Position:



Function:

For Filtration	After Filtration	After the Filtration Run	For Autoclaving
The full vacuum draws the sample through the membrane filter. The venting filter is "off-line."	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.	The residual vacuum between the pump and valve is released via the sterilizing grade filter.	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 ☐ No ☐
2. Vacuum is build up in the system Yes ☐ No ☐
3. Biosart® 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 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 ☐ No ☐
2. No vacuum occurs on the venting filter Minisart® SRP — Yes ☐ No ☐
3. All Combisart® taps were tested — 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.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 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 ☐ No ☐
2. Vacuum occurs on the venting filter Minisart® SRP 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.

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. <u>All</u> 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 ☐

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: _____