

IQ | OQ DOCUMENTATION

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

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INSTALLATION QUALIFICATION DOCUMENT

Vacuum Filtration Equipment

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Individual Vacuum Filtration System
Biosart® 100 Monitors

IQ | OQ Documentation

IQ Protocol

**Installation Qualification
Content**

CLIENT INFORMATION

Client name: _____

Type of vacuum filtration system: Individual Combisart® System

No. of filter stations: 1

Type of funnel: Biosart® 100 Monitor

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.: _____

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: _____

Individual Vacuum Filtration System
Biosart® 100 Monitors

IQ | OQ Documentation

IQ Protocol

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: _____

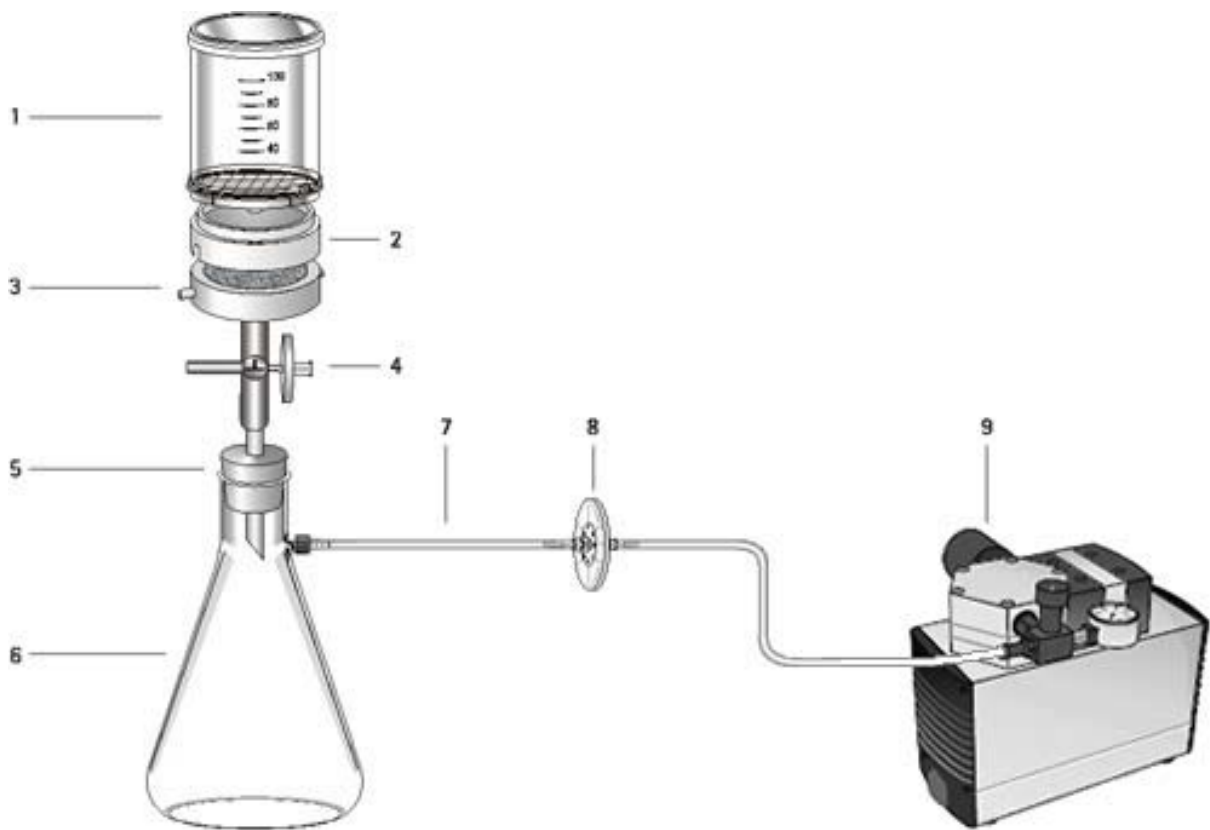
Date: _____

COMPANY: _____

2. A- DELIVERY CONTROL

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

Set Up of an individual filtration system on top of a 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 for Biosart® 100

- | | | | | |
|--------------------------|-----|--------------------------|----|--------------------------|
| 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® Individual Base

A.[4] 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"/> |

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.[5] Silicone Stopper

- | | | | | |
|-----------------------|-----|--------------------------|----|--------------------------|
| 1. Silicone stopper: | 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.[6] Choice one out of two Suction Flasks (please delete where inapplicable)

2-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"/> |

1-Liter 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"/> |

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: _____

Individual 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.[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

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

Individual Vacuum Filtration System
Biosart® 100 Monitors

IQ | OQ Documentation

OQ Protocol

**Operational Qualification
Content**

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: _____

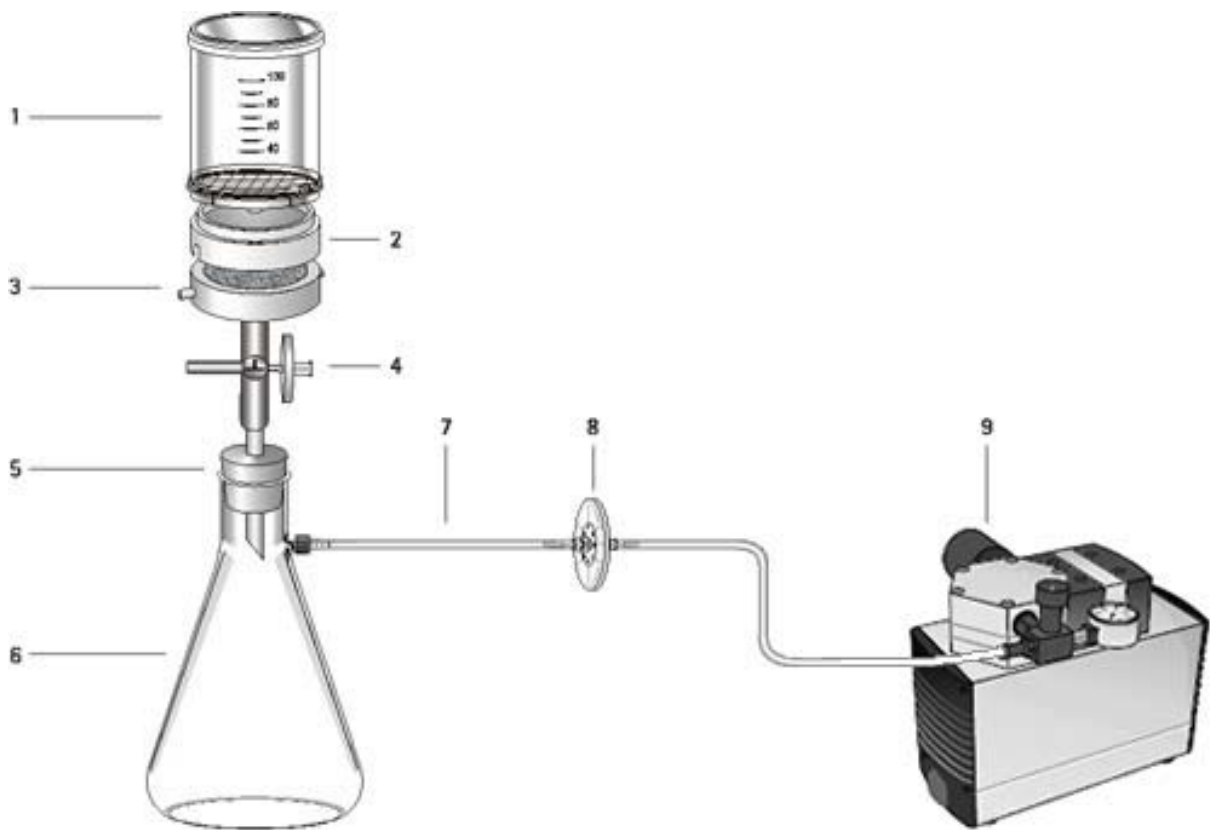
Witness Signature: _____ Date: _____

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



Operator Signature: _____

Date: _____

COMPANY: _____

Witness Signature: _____

Date: _____

COMPANY: _____

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

Operator Signature: _____

Date: _____

COMPANY: _____

Witness Signature: _____

Date: _____

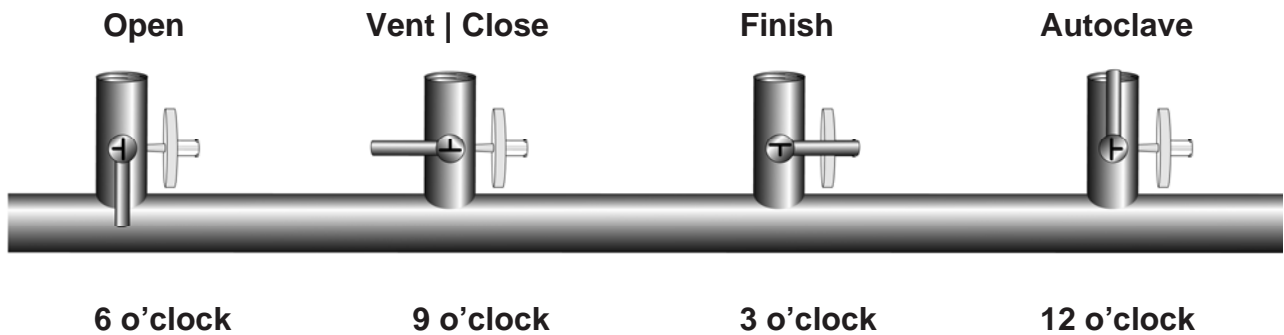
COMPANY: _____

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 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 | <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 is 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.

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

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

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 <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"/> |

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"/> |

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 a Biosart® 100 Monitor [1] on top of the Biosart® 100 Adapter [2] and turning the Combisart® tap 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"/> |

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"/> |

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: _____