### **Operating Instructions**

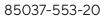
Original Operating Instructions

# Process Filter Holder | Double Process Filter Holder

2ZGL--0006 | 2ZGL--0007

Cassette Holder for Sartoclear® Depth Filter | Sartobind® Membrane Adsorbers









# Contents

| 1 | Abo  | out this | S Document                                  | 5  |
|---|------|----------|---|----|
|   | 1.1  |          | <b>.</b>                                    |    |
|   | 1.2  | Accon    | mpanying Documents                          | 5  |
|   | 1.3  | Target   | t Groups                                    | 5  |
|   | 1.4  | Symbo    | ols Used                                    | 6  |
|   |      | 1.4.1    | Warnings                                    | 6  |
|   |      | 1.4.2    | Other Symbols                               | 6  |
|   |      | 1.4.3    | Figures in these Instructions               | 6  |
| _ |      |          |   | _  |
| 2 |      | -        | tructions                                   |    |
|   | 2.1  |          | ded Use                                     |    |
|   |      |          | nnel Qualification                          |    |
|   |      | •        | icance of these Instructions                |    |
|   |      |          | essness of the Device                       |    |
|   |      | -        | / Equipment                                 |    |
|   |      |          | ssories, Consumables, and Spare Parts       |    |
|   |      |          | uct in an Emergency                         |    |
|   |      |          | nal Protective Equipment                    |    |
|   |      | ,        | nulic Energy                                |    |
|   |      |          | ng the Device                               |    |
|   |      |          | ling of Heavy Components                    |    |
|   |      |          | tive Tubing Lines and Screw Connections     |    |
|   |      |          | g Away of the Device                        |    |
|   | 2.14 | Dome     | ed Feet on the Device                       | 10 |
| 2 | D    | D.       |   | 11 |
| 3 |      |          | escription                                  |    |
|   | 3.1  |          | e Overview                                  |    |
|   |      |          | nulic Pump with Pressure Gage               |    |
|   |      |          | view with Installed Cassettes               |    |
|   |      |          | old Plates                                  |    |
|   |      |          | oing Plate                                  |    |
|   |      |          | ure Plate                                   |    |
|   |      |          | clear® Baffle Plate                         |    |
|   | 3.8  | -        | / Equipment                                 |    |
|   |      | 3.8.1    | Domed Feet                                  | 14 |
| 4 | Inst | allation | n   | 15 |
|   | 4.1  |          | e of Delivery                               |    |
|   |      |          | quisites for Assembly                       |    |
|   |      |          | cking the Device                            |    |
|   |      |          | ing the Device at the Place of Installation |    |
|   |      |          | in Domed Feet for Moving the Device         |    |
|   |      |          | ng up the Hydraulic Pump.                   | 16 |

| 5  | Operation  | 17   |
|----|--|------|
|    | 5.1 Note on the Figures  | 17   |
|    | 5.2 Moving Holding Clamps  | 17   |
|    | 5.3 Operating the Hydraulic Pump   | 18   |
|    | 5.3.1 Releasing the Hydraulic Pump   | 18   |
|    | 5.3.2 Releasing the Hydraulic Cylinder   | 18   |
|    | 5.3.3 Checking the Tensioning Pressure   | 19   |
|    | 5.4 Inserting and Tensioning the Cassettes   | 19   |
|    | 5.4.1 Adjusting the Pressure Plate and Clamping Plate  | 19   |
|    | 5.4.2 Inserting the Cassettes  | . 20 |
|    | 5.4.3 Observing the Permissible Stroke of the Hydraulic Cylinder   |      |
|    | 5.4.4 Tensioning the Cassettes   | . 23 |
|    | 5.5 Performing the Filtration or Adsorption Process  |      |
|    | 5.6 Removing the Cassettes   | . 24 |
| ,  |  | 25   |
| 6  | Cleaning   | . 25 |
| 7  | Malfunctions   | 26   |
| •  | T Idil di Idil | 0    |
| 8  | Transportation   | . 27 |
|    |  |      |
| 9  | Storage and Shipping   |      |
|    | 9.1 Storage  |      |
|    | 9.2 Storage Instructions   |      |
|    | 9.3 Shipping-related Tasks   Returns   | . 28 |
| 10 | Disposal   | 20   |
| 10 | 10.1 Information on Decontamination  |      |
|    | 10.2 Decommissioning the Device  |      |
|    | 10.3 Disposing of the Device and Parts   |      |
|    | 10.3.1 Information on Disposal   |      |
|    | 10.3.2 Disposal.   |      |
|    |  |      |
| 11 | Technical Data   | 31   |
|    | 11.1 Dimensions and Weight   | 31   |
|    | 11.2 Hydraulic Cylinder Dimensions   | 31   |
|    | 11.3 Accommodation of Cassettes  | 31   |
|    | 11.4 Ambient Conditions During Operation   | . 32 |
|    | 11.5 Design and Lifespan   | . 32 |
| 10 |  | 22   |
| 12 | Accessories  | . 33 |
| 13 | Consumables  | . 33 |
|    |  | . 55 |
| 14 | Sartorius Service  | . 33 |
|    |  |      |
| 15 | Conformity   | . 34 |

# 1 About this Document

### 1.1 Scope

The manual applies to the device in the following versions:

| Device                       | Туре     |
|------------------------------|----------|
| Process Filter Holder        | 2ZGL0006 |
| Double Process Filter Holder | 2ZGL0007 |

### 1.2 Accompanying Documents

This manual contains the instructions for operating the device with the standard equipment intended for this purpose.

- ▶ In addition to this manual, observe the following documents:
  - Operating Instructions for the Sartoclear® Depth Filter cassettes used
  - Operating Instructions for the Sartobind® adsorption cassettes used,
     e.g., Sartobind® Q and S, Sartobind STIC® PA, Sartobind® Phenyl
  - Hydraulic pump Operating Instructions
  - Instructions for the filtration or adsorption system with which the device is operated

### 1.3 Target Groups

These instructions are designed for the following target groups. The target groups must possess the knowledge listed.

| Target Group | Knowledge   responsibilities   |
|--------------|--|
| User         | The user is familiar with the operation of the device and the associated work processes. The user knows the dangers that can occur when working with the device and can avoid these dangers.  The user has been trained in the operation of the device.  Training takes place within the scope of startup and is carried out by the operating engineer   laboratory manager or the operator of the device. |
| Operator     | The operator of the device is responsible for compliance with safety requirements and workplace safety regulations.  The operator must ensure that all persons who work with the device have access to the relevant information and have been instructed in work with the device.  |

### 1.4 Symbols Used

### 1.4.1 Warnings

#### **MARNING**

Denotes a danger with risk that death or (severe) injury may result if it is not avoided.

#### **△** CAUTION

Denotes a danger with risk that moderate or minor injury may result if it is not avoided.

#### **NOTICE**

Denotes a danger that can result in property damage if the risk is not avoided.

### 1.4.2 Other Symbols

- Required action: Describes tasks that need to be carried out in the order listed.
- Result: Describes the result of the activities carried out.

### 1.4.3 Figures in these Instructions

Depending on the product configuration, the figures depicting the product and operating display may differ slightly from the supplied product. The variants shown in these instructions are examples.

# 2 Safety Instructions

#### 2.1 Intended Use

The device is a hydraulic tensioning device and is intended to tension cassettes that are used in filtration and adsorption processes of membrane chromatography. Sartoclear® filter cassettes must be used for filtration; Sartobind® adsorption cassettes must be used for adsorption chromatography. The cassettes must not be mixed.

The device is **not fitted with any** connections for unfiltered or filtered solutions. Manifold plates must be used for filtration.

Only approved cassettes and manifold plates may be used (approved cassettes and manifold plates, see Chapter "13 Consumables", page 33). Some of the cassettes and manifold plates are single-use products and must be disposed of after one use. Some cassettes may be reused; their reusability is specified in the instructions for the cassette.

The required tensioning pressure must only be generated using the hydraulic pumps specified by Sartorius. The use of other hydraulic pumps poses a risk to operational safety and the safety of the operator and reduces the quality of the end product.

**Do not** install unauthorized objects in the device. Do **not** use this device in potentially explosive environments. The device may only be used indoors.

Only use the device with the equipment and under the operating conditions described in the Technical Data. Do **not** modify the device or make any technical changes.

Any further use beyond this is considered **improper** and is forbidden. These instructions are part of the device. The device is intended exclusively for use in accordance with these instructions.

#### Foreseeable Misuse

The use of the device is only safe when it is used properly. The following applications, for example, are **not** permitted:

- Use of the device as a transport aid
- Use of the device as a climbing aid

## 2.2 Personnel Qualification

All persons working on the device must possess the necessary knowledge (for a description, see Chapter "1.3 Target Groups", page 5).

The activities described are addressed to the operator. If individual actions must be carried out by other target groups or by Sartorius Service personnel, this will be indicated.

### 2.3 Significance of these Instructions

Failure to follow the instructions in this manual can have serious consequences, e.g. exposure of individuals to electrical, mechanical or chemical hazards.

- ▶ Before working with the device: Read the instructions carefully and completely.
- ▶ If the instructions are lost: Request a replacement or download the latest instructions from our website.
- ► The information in these instructions must be accessible to users or the target groups named.

### 2.4 Flawlessness of the Device

Damaged equipment or worn-out parts can cause malfunctions or lead to hard-to-detect hazards.

- ▶ Only operate the device when it is safe and in perfect working order.
- ▶ Have any malfunctions or damage repaired immediately by the Sartorius Service.

### 2.5 Safety Equipment

The safety equipment on the device protects persons who work with the device against the hazards and harms associated with it, e.g. electrical current.

► The device's safety equipment must not be dismantled or modified (Safety Equipment, see Chapter 3.8, page 14).

# 2.6 Accessories, Consumables, and Spare Parts

The use of unsuitable accessories, consumables, and spare parts can be hazardous and have the following consequences:

- Damage to the device
- Malfunction of the device
- Device failure
- Only use Sartorius accessories, consumables, and spare parts. Information on operational quality is available upon request from Sartorius.
- ▶ Only use accessories, consumables, and spare parts that are in proper working order.

### 2.7 Conduct in an Emergency

Malfunctions may result in injury or property damage. If there is immediate danger of personal injury or damage to the device, take the device out of operation immediately:

- ► Turn off the higher-level control.
- ▶ Have malfunctions repaired immediately by the Sartorius Service.

### 2.8 Personal Protective Equipment

Personal protective equipment protects against risks arising from the equipment and the material being processed.

| Protective equipment designation | Explanation   examples  |
|----------------------------------|---|
| Protective work clothing         | Tight-fitting work clothing with low tear resistance, tight sleeves, and without any projecting parts. Protects against getting caught in moving parts. |
| Head covering                    | Protects hair from being pulled into moving parts.  |
| Safety gloves                    | Protect against chemicals, heat, and injuries.  |
| Safety glasses                   | Protect against substances escaping under high pressure, and liquid spray and splashes.   |
| Safety boots  <br>non-slip shoes | Protect against injuries to the feet caused by mechanical effects.   Protect against slipping on wet surfaces.  |

- ▶ Wear appropriate personal protective equipment.
- Also follow any instructions posted in the work area pertaining to personal protective equipment.

# 2.9 Hydraulic Energy

Releasing and tensioning the cassettes using the hydraulic cylinder present a risk of crushing.

- Never reach inside the hydraulic area or grab moving parts.
- ▶ Do **not touch** moving parts when releasing and tensioning the cassettes.
- ▶ Before performing any work on the hydraulic system: Depressurize hydraulic system.
- Before tensioning or removing the cassettes: Release the hydraulic cylinder.

### 2.10 Moving the Device

The device has moving components and a high intrinsic weight. When moving the device, there is a risk of crushing.

- ▶ Use the handle to move the device. Do **not** touch the device on the pull rods or pressure plates.
- Ensure that **no** individuals get in its path.

### 2.11 Handling of Heavy Components

The device has a high intrinsic weight. When lifting the device, there is a risk of injury.

- Lift the device only with lifting accessories.
- ▶ When lifting the cassettes and manifold plates, get assistance from other persons.
- Never lift the device on the pull rods or pressure plates. Only ever lift the device on the frame where the guide rollers are mounted.
- Wear personal protective equipment.

### 2.12 Defective Tubing Lines and Screw Connections

Defective tubing lines and screw connections can result in uncontrollable spillage of media. Escaping media can result in dangers like scalding, chemical burns etc.

► Check whether the hoses, tubes, and screw connections on the device are damaged.

# 2.13 Rolling Away of the Device

Any uncontrolled rolling away of the device can lead to injuries.

- ▶ Only place the device on level surfaces.
- ▶ Secure the device by setting the domed feet.
- ► Wear personal protective equipment.

#### 2.14 Domed Feet on the Device

Improper operation of the domed feet can result in injuries.

- ▶ Only operate the domed feet with your foot.
- Wear personal protective equipment.

# 3 Device Description

# 3.1 Device Overview

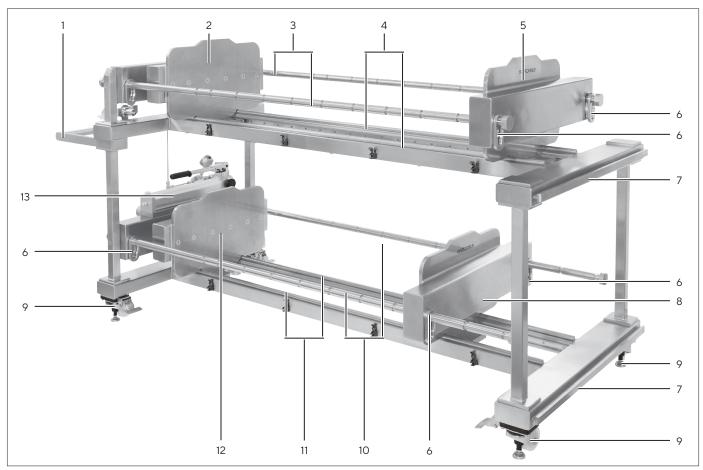


Fig. 1: Double Process Filter Holder (example)

| No. | Designation                       | Description   |
|-----|-----------------------------------|---|
| 1   | Handle                            |   |
| 2   | Pressure plate, top               | Hydraulically adjustable.   |
| 3   | Pull rods, top                    |   |
| 4   | Guide rods, top                   |   |
| 5   | Clamping plate, top               | Manually adjustable.  |
| 6   | Holding clamp                     | Fixes the base and clamping plates to the pull rods.                          |
| 7   | System rail                       | Accommodates accessories, e.g., holders for sterile filters or tubing holder. |
| 8   | Clamping plate, bottom            | Manually adjustable.  |
| 9   | Guide rollers                     |   |
| 10  | Pull rods, bottom                 |   |
| 11  | Guide rods, bottom                |   |
| 12  | Pressure plate, bottom            | Hydraulically adjustable.   |
| 13  | Hydraulic pump with pressure gage |   |

# 3.2 Hydraulic Pump with Pressure Gage

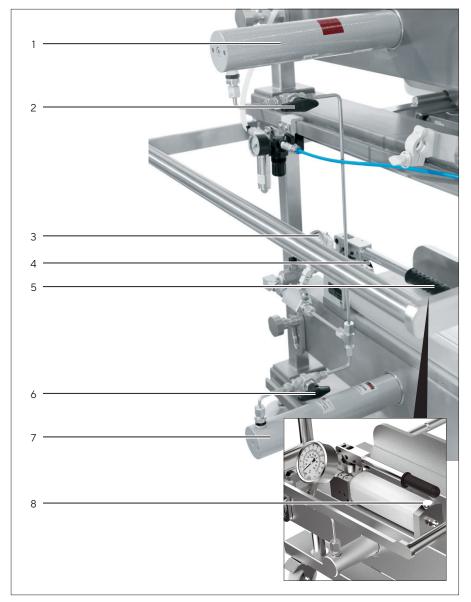


Fig. 2: Hydraulic system at the Double Process Filter Holder (example)

| No. | Designation                        | Description  |
|-----|------------------------------------|--|
| 1   | Hydraulic cylinder, top            | For Double Process Filter Holder only                  |
| 2   | Needle valve, top                  | For Double Process Filter Holder only                  |
| 3   | Pressure gage                      |  |
| 4   | Release valve of<br>hydraulic pump |  |
| 5   | Pump lever                         |  |
| 6   | Needle valve, bottom               |  |
| 7   | Hydraulic cylinder, bottom         |  |
| 8   | Ventilation screw                  | Opens and closes the vent valve on the hydraulic pump. |

# 3.3 Overview with Installed Cassettes



Fig. 3: Double Process Filter Holder with installed Sartoclear® filter cassette (example)

| No. | Designation                       | Description  |
|-----|-----------------------------------|--|
| 1   | Manifold plate for inlet, top     | Draws the liquid in. For filtration: Unfiltered solution |
| 2   | Cassette, top                     | Filter cassette or adsorption cassette                   |
| 3   | Manifold plate for outlet, top    | Purges the liquid. For filtration: Filtered solution     |
| 4   | Clamping plate, top               |  |
| 5   | Clamping plate, bottom            |  |
| 6   | Manifold plate for outlet, bottom | Purges the liquid. For filtration: Filtered solution     |
| 7   | Cassette, bottom                  | Filter cassette or adsorption cassette                   |
| 8   | Manifold plate for inlet, bottom  | Draws the liquid in. For filtration: Unfiltered solution |
| 9   | Pressure plate, bottom            |  |
| 10  | Pressure plate, top               |  |
|     |                                   |  |

### 3.4 Manifold Plates

The manifold plates rest against the pressure and clamping plates. The cassettes are seated between the manifold plates. The filtration and adsorption processes **cannot** be performed without manifold plates.

### 3.5 Clamping Plate

The clamping plate is fastened on to the pull rods by the holding clamps. The position of the clamping plate depends on the number of installed cassettes.

### 3.6 Pressure Plate

By moving out the hydraulic cylinder, the pressure plate is pressed against the inserted cassettes and the clamping plate.

### 3.7 Sartoclear® Baffle Plate

The Sartoclear® baffle plate is intended to install pressure sensors.

### 3.8 Safety Equipment

#### 3.8.1 Domed Feet

The domed feet are designed to secure the device and prevent it from rolling away.

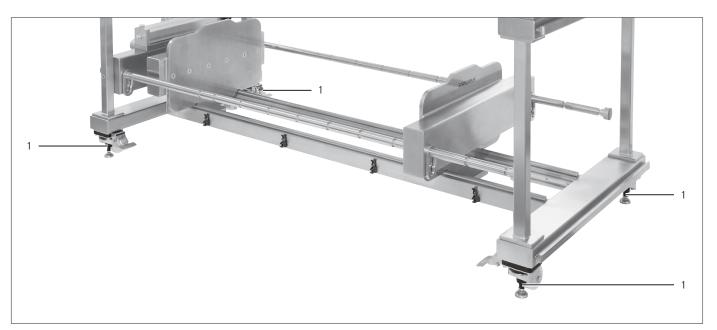


Fig. 4: Domed feet

| No. | Designation |
|-----|-------------|
| 1   | Domed feet  |

# 4 Installation

# 4.1 Scope of Delivery

| Item   | Quantity |
|--|----------|
| Process Filter Holder   Double Process Filter Holder | 1        |
| Operating Instructions                               | 1        |

# 4.2 Prerequisites for Assembly

#### Procedure

▶ Ensure that the following conditions are met at the workplace:

| Condition                               | Features   |  |
|---|--|--|
| Footprint                               | <ul> <li>Even surface</li> <li>Sufficient space for the device and peripheral devices (see Chapter 11.1, page 31 for dimensions).</li> <li>Sufficient load bearing for the device and peripheral devices, even when filled (see Chapter 11.1, page 31 for device weight).</li> </ul> |  |
| Access to parts relevant to operation   | Convenient and safe  |  |
| Resistance of work surfaces             | Resistant against the media used, such as acids  |  |
| Cleaning and disinfecting work surfaces | Easy to clean, can be disinfected if contaminated  |  |
| Ambient conditions                      | Suitability tested according to Chapter 11.4, page 32.   |  |

# 4.3 Unpacking the Device

- ► Remove all packaging parts.
- ▶ Remove the transport lock with which the device is fixed in place.

# 4.4 Securing the Device at the Place of Installation

The device must be secured at the place of installation. To do so, move out the domed feet.

#### Procedure

- ► ▲ CAUTION Danger of crushing when operating the domed feet! Wear personal protective equipment.
- ▶ Press down on the lever with your foot.
- > The device is secured against moving.

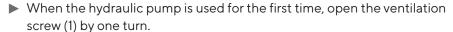
### 4.5 Draw in Domed Feet for Moving the Device

To move the device, the domed feet must be drawn in.

#### Procedure

- ► ▲ CAUTION Danger of crushing when operating the domed feet! Wear personal protective equipment.
- ► Lift the lever up with the foot.

### 4.6 Starting up the Hydraulic Pump



> This allows aeration and venting of the hydraulic tank.

Once the work is completed or at the latest before transport, screw the ventilation screw (1) back on tightly.



# 5 Operation

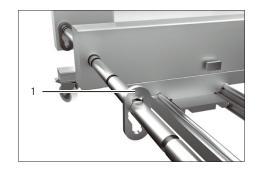
# 5.1 Note on the Figures

The figures on the following pages partially present the Sartorius Pilot Filter Holder. The procedure is identical to the Process | Double Process Filter Holder.

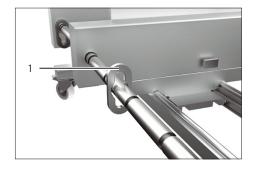
# 5.2 Moving Holding Clamps

#### Procedure

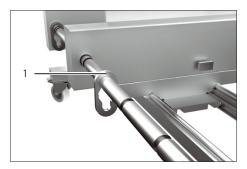
▶ Pull the holding clamp (1) halfway up.



Move the holding clamp (1) along the pull rod to the desired position.



- ▶ Allow the holding clamp (1) to fall to the desired depth.
- > The holding clamp is in the new position.



## 5.3 Operating the Hydraulic Pump

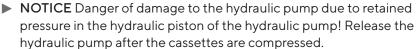
### 5.3.1 Releasing the Hydraulic Pump

#### **Prerequisites**

 The hydraulic pump is operational (see Chapter "4.6 Starting up the Hydraulic Pump", page 16).

#### Procedure







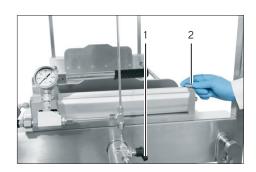
- ▶ Open the vent valve on the hydraulic pump. Turn the ventilation screw (1) counterclockwise.
- This builds up pressure in the hydraulic piston.
- ► ▲ CAUTION Danger of injury due to upright pump lever! Push the pump lever down into its original position.

#### 5.3.2 Releasing the Hydraulic Cylinder

#### Prerequisites

- The cassettes have been depressurized.
- The cassettes have been drained of any residue.

- ▶ If leakage of liquid residue is likely: Place the collecting tank under the filter holder.
- ➤ Open the vent valve on the hydraulic pump. Turn the ventilation screw (2) counterclockwise.
- ► ▲ CAUTION Danger of crushing from the moving hydraulic cylinder! Open the needle valve (1) on the hydraulic cylinder. To do so, turn the needle valve clockwise.
- ➤ The hydraulic cylinder releases and draws back.
- ➤ Wait until the pressure gage display reads zero and the hydraulic cylinder is fully loosened.
- ▶ Close the needle valve. To do so, turn the needle valve clockwise.



#### 5.3.3 Checking the Tensioning Pressure

The tensioning pressure applied during compression may reduce during operation, with the result that the cassettes are **not** sufficiently compressed. Reduced tensioning pressure may negatively impact on the performance of the cassettes.

#### Procedure

- ▶ During the filtration or adsorption process, check regularly whether the required tensioning pressure is being achieved (see instructions for the cassette). To do so, observe the pressure gage display.
  - ▶ If required: Re-adjust the cassettes (see Chapter "5.4.4 Tensioning the Cassettes", page 23).

### 5.4 Inserting and Tensioning the Cassettes

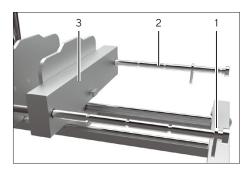
### 5.4.1 Adjusting the Pressure Plate and Clamping Plate

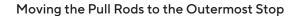
Depending on the number of cassettes to be inserted, the distances between the pressure plate and clamping plate have to be adjusted in relation to each other.

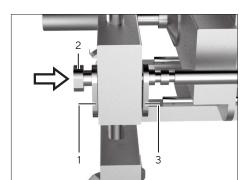
#### **Prerequisites**

- The hydraulic cylinder is released (see Chapter "5.3.2 Releasing the Hydraulic Cylinder", page 18).
- There are no used cassettes in the device.

- ▶ NOTICE Danger of damage to the hydraulic cylinder! Never pressurize the hydraulic cylinder without inserted cassettes. Since the hydraulic cylinder only has a limited stroke, the cassettes must be positioned very tightly together.
- ▶ Move the pressure plate and clamping plate to the outermost stop. To do so, proceed as follows:
  - Move the holding clamps on the clamping plate to the pull rod's outermost position (1) (see Chapter "5.2 Moving Holding Clamps", page 17).
  - Repeat the process with the second pull rod (2).
  - ▶ Push the clamping plate (3) on to the holding clamps.







#### Procedure

- ► Move the outer holding clamps (1) on the two pull rods to the respective left-hand position (see Chapter 5.2, page 17).
- ▶ Move both pull rods (2) as far as the stop on the right at the same time.
- ► Move the inner holding clamps on the two pull rods to the respective left-hand position (3).

#### 5.4.2 Inserting the Cassettes

#### **NOTICE**

#### Danger of damage to the cassette!

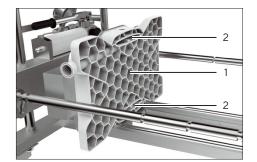
Improper handling of the cassette during installation may damage the cassette.

- ► Hold the cassettes by the handles. Sartobind® adsorption cassettes and depth filter cassettes (Sartoclear® Depth Filter) can also be held at the sides.
- ▶ Only place the cassettes on clean surfaces.
- ▶ **Do not apply** any pressure to the cassettes. **Do not** allow the cassettes to fall.
- ► Take great care when inserting the cassettes.

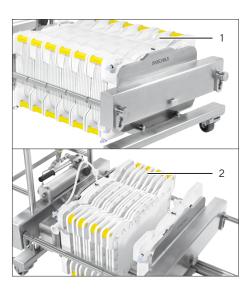
#### NOTICE

#### Danger of damage to the filtration or adsorption system!

➤ The filtration or adsorption system must not be operated without a cassette.

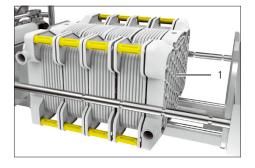


- ▶ NOTICE Danger of damage to the filtration or adsorption system! If the manifold plate is aligned incorrectly, the flow rate is disturbed and this may cause liquid to leak or cause damage to the manifold plate and cassettes.
- ▶ Place the manifold plates (1) for the fluid inlet according to their labeling onto the bottom guide rods (for labeling see the instructions for the manifold plate).
- ▶ The channels (2) must be aligned in the direction of the cassettes.
- ▶ Push the manifold plate onto the pressure plate.

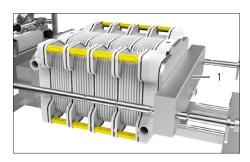


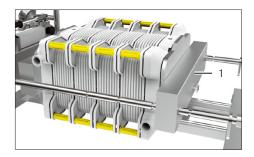
- ► Insert the desired number of Sartoclear® filter cassettes (1) or Sartobind® adsorption cassettes (2) one after the other, according to their labeling, on the bottom guide rods. Please observe the following notes:
  - ▶ Pay attention to the alignment (up | down) of the cassettes (see the instructions for the cassettes used).
  - ▶ Do not exceed the maximum number of cassettes to be tensioned (for number, see Chapter "11.3 Accommodation of Cassettes", page 31).

- ▶ If a Sartoclear® baffle plate is to be used, the Sartoclear® baffle plate should be placed between the Sartoclear® filter cassette or Sartobind® adsorption cassettes. Pay attention to the alignment of the Sartoclear® baffle plate (see the instructions for the cassettes used).
- ▶ Push the cassettes towards each other until there is **no longer any** free space between them.
- ► Check the position of the cassettes. The notches of the cassettes must be positioned on the bottom guide rods of the device.
- ▶ Ensure that the cassettes are seated evenly and flush inside the device.
- ▶ Place the manifold plate (1) for the fluid outlet according to its labeling onto the bottom guide rods (see the instructions for the manifold plate).
- ▶ Push the manifold plate onto the cassettes.



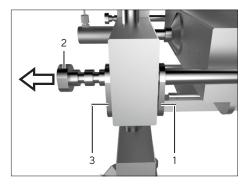
▶ Push the clamping plate (1) on to the manifold plate.





▶ Position the holding clamps as closely as possible to the clamping plate (1) (see Chapter "5.2 Moving Holding Clamps", page 17).

#### Moving the Cassettes Towards the Pressure Plate



#### Procedure

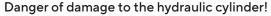
- Move the inner holding clamps (1) on the two pull rods to the respective right-hand position (see Chapter "5.2 Moving Holding Clamps", page 17).
- ▶ Move the cassettes as close as possible to the pressure plate by pulling on both pull rods (2) at the same time. The cylinder stroke should be kept as small as possible.
- ▶ Move the outer holding clamps (3) on the two pull rods to the right-hand position.

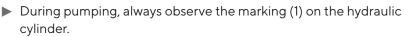
# 5.4.3 Observing the Permissible Stroke of the Hydraulic Cylinder

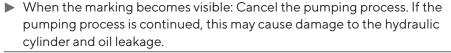
Depending on the number of cassettes used, there is a risk that the hydraulic cylinder must be moved so far out for tensioning that the maximum permissible stroke of the hydraulic cylinder is exceeded and the cassettes **cannot** be tensioned sufficiently.

When the marking on the hydraulic cylinder becomes visible: The distance between the base plate and clamping plate is too great and must be set to a shorter distance with the holding clamps.

#### **NOTICE**









#### Procedure

▶ Prior to pressurization on the hydraulic cylinder: Set the fine adjustment on the guide rods. Doing so prevents the permissible stroke of the hydraulic cylinder from being exceeded.

#### 5.4.4 Tensioning the Cassettes

#### **NOTICE**

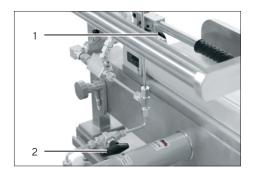
#### Danger of damage to the filtration or adsorption system!

**Never** tension the cassettes without inserting and screwing guide rods into the device.

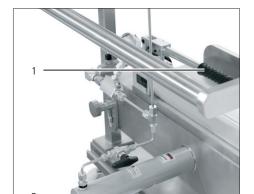
#### **Prerequisites**

- The manifold plates and cassette(s) are inserted in the right position.
- The holding clamps are positioned according to the number of cassettes used. The cylinder stroke of the hydraulic cylinder is kept as short as possible.
- There are **no** tools, transfer lines, or other objects in the tensioning area of the device.

- ▶ Close the release valve (1). To do so, turn the release valve clockwise.
- Open the needle valve (2). To do so, turn the needle valve counterclockwise.
- ▶ Observe the information regarding the permissible tensioning force for the cassettes used (see the instructions for the cassette) and the following information regarding the tensioning force (kilonewton; kN)/12.6 cm² filter area:



| 4- |     |        |           |
|----|-----|--------|-----------|
| 15 | 95  | 30     | 189       |
| 20 | 126 | 35     | 221       |
| 25 | 158 | 40     | 252       |
|    | 20  | 20 126 | 20 126 35 |



- ➤ Check the pressure gage display when compressing the cassette(s) in order to ensure that the applied tensioning force does **not** exceed the permissible value (for the permissible tensioning force see the instructions for the cassette).
- ➤ Slowly pump the lever (1) on the hydraulic pump with approx. 1 stroke every 2 seconds to build up the required pressure. The modules may get damaged if operation is too quick.
- The hydraulic cylinder (2) moves forward and the pressure plate compresses the Sartoclear<sup>®</sup> filter cassettes.
- ▶ When compressing the filter cassette, check the marking on the hydraulic cylinder (see Chapter "5.4.3 Observing the Permissible Stroke of the Hydraulic Cylinder", page 22).
- ▶ When the pressure gage indicates the permissible tensioning force or the permissible stroke is exceeded: Stop the pressure buildup (stop pumping).
- ▶ Release the hydraulic pump (see Chapter 5.3.1, page 18).
- > The cassette is completely mounted and compressed in the device.

# 5.5 Performing the Filtration or Adsorption Process

#### Procedure

- ► Connect the tubing lines to the manifold plates (see the Operating Instructions for the cassettes used).
- ▶ Perform the filtration or adsorption process (see instructions for the filtration or adsorption system).

### 5.6 Removing the Cassettes

#### **Prerequisites**

The cassettes have been depressurized and completely drained.

- ▶ Place the collecting tank under the device so that any liquid residue is caught when releasing the hydraulic cylinder.
- ▶ Drain the system (see the Operating Instructions for the cassettes used).
- ▶ Disconnect the tubing lines from the manifold plates.
- ▶ Release the hydraulic cylinder (see Chapter 5.3.2, page 18).
- ▶ To make it easier to remove the cassettes, proceed as follows:
  - ▶ Move the holding clamps into an outer position.
  - ▶ Move the pressure plate and clamping plate outwards.
- ► ▲ CAUTION Risk of injury due to heavy components. Remove the following components from the device one after the other:
  - Manifold plate for outlet
  - Cassette(s)
  - Manifold plate for inlet
- Dispose of the manifold plates and cassettes together with the associated tubing lines.

# 6 Cleaning

Regular cleaning is essential. Operational reliability depends, in addition to several other factors, also on proper cleaning.

Cleaning intervals largely depend on the stress placed on the equipment by aggressive components contained in the media (e.g. acids and bases used to regulate pH) and the level of contamination from culture and metabolic product residues attached to this equipment.

#### **NOTICE**

# Danger of corrosion and damage to the device by unsuitable cleaning agents!

- Avoid highly caustic or chloride-containing detergents.
- Avoid solvent-based cleaning agents.
- Ensure that the cleaning agents used are compliant materials.

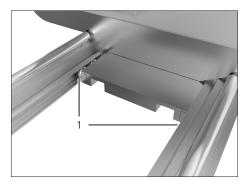
#### Procedure

- Observe the safety instructions for the cleaning agents. The use and disposal of cleaning agents, and water containing such agents, may be subject to legal or environmental protection regulations in your country.
- ▶ Be sure not to scratch the device.
  Future contamination is otherwise more difficult to remove.
- ▶ Take the following preliminary steps when performing cleaning work:
  - Release the hydraulic cylinder.
  - ▶ If required: Remove the cassette(s).
- ► Clean the device with a slightly damp cloth. For more severe contamination, use a mild soap solution.

#### Rinsing the Roller Bearings on the Bottom Guide Rods

#### Procedure

▶ Use a mild soap solution to rinse the roller bearings (1) on the guide rods.



# 7 Malfunctions

| Problem  | Cause   | Correction   | Chapter, Page |
|--|---|--|---------------|
| Liquid exits at the bottom of the  | The tensioning pressure is <b>not</b> sufficient. | Check the pressure gage display.<br>If required: Increase the inlet pressure.  | 5.4, 19       |
| tensioned cassette(s).   |   | Observe the tensioning force (kN) of the inserted cassette(s) (see instructions for the cassette).                     |               |
| The hydraulic piston has moved out completely without the Sartoclear® filter cassettes being sufficiently compressed.  The cassettes have not been inserted and aligned correctly. | Set the fine adjustment to a narrower distance.   | 5.2, 17  |               |
|  | Check whether the maximum permissible             | 5.4, 19  |               |
|  | <u> </u>  | stroke is exceeded.  | 11.2, 31      |
|  | been inserted and aligned                         | Insert the manifold plate and the cassettes into the device to the lowest point and align them so that they are flush. | 5.4, 19       |
| Hydraulic oil is<br>leaking from the<br>hydraulic cylinder.  | The hydraulic cylinder is faulty.                 | Contact Sartorius Service.   |               |

Consult Sartorius Service regarding any problems you **cannot** solve yourself. Do **not** carry out any unauthorized repair work on the device.

# 8 Transportation

#### Prerequisites

- All cassettes have been removed.
- The device has been shut off.

- ➤ Tighten the ventilation screw of the hydraulic pump securely (see Chapter "4.6 Starting up the Hydraulic Pump", page 16).
- ▶ Draw in the domed feet (see Chapter 4.5, page 16).
- ► ▲ CAUTION Danger of crushing from the moving clamping plate!

  Use the handle to move the device. Do **not** touch the device on the pull rods or pressure plates.
- ► ▲ CAUTION Risk of injury to other persons caused by the device! Ensure that **no** individuals get in its path.
- ► Transport the device to its new location.
- ▶ Secure the device at the installation site (see Chapter 4.4, page 16).

# 9 Storage and Shipping

### 9.1 Storage

#### Procedure

- ▶ Decommission the device.
- ▶ If required: Pack the device.

### 9.2 Storage Instructions

- Dry buildings
- Do not expose to UV radiation and direct sunlight
- Do not store in rooms where solvents, chemicals, acids, and fuels are stored.

# 9.3 Shipping-related Tasks | Returns

Defective devices or parts can be sent back to Sartorius. Returned devices must be clean, decontaminated, and properly packed.

Transport damage as well as measures for subsequent cleaning and disinfection of the device or parts by Sartorius shall be charged to sender.

#### ▲ WARNING

#### Risk of injury due to contaminated equipment!

Devices contaminated with hazardous materials (NBC contamination) will **not** be accepted for repair or disposal.

▶ Observe the information on decontamination (see Chapter "10.1 Information on Decontamination", page 29).

- ▶ Decommission the device (see Chapter "10.2 Decommissioning the Device", page 29).
- Complete the Decontamination Declaration. Use the forms available on our website (www.sartorius.com).
- ► Enclose the Decontamination Declaration with the delivery documents. The recipient must be able to inspect the completed Decontamination Declaration before removing the device from the packaging.
- Pack the device and its parts properly.
- ▶ Return the device to Sartorius Service. The service addresses for returns can be found on our website (www.sartorius.com).

# 10 Disposal

#### 10.1 Information on Decontamination

The device does **not** contain any hazardous materials that would necessitate special disposal measures. The cultures and media (e.g. acids, bases) used during the fermentation processes are potentially hazardous materials that could cause biological or chemical hazards.

According to the EU directives [European directive on hazardous substances], the owners of devices that come into contact with hazardous substances are responsible for properly disposing of these devices and must declare such devices when transporting them.

#### **△** WARNING

#### Risk of injury due to contaminated devices!

Devices contaminated with hazardous materials (NBC contamination) will **not** be accepted for repair or disposal.

### 10.2 Decommissioning the Device

#### Procedure

- ► Release the hydraulic cylinder.
- ▶ Remove the all the cassettes.
- ▶ Clean the device.
- Decontaminate the device.

# 10.3 Disposing of the Device and Parts

#### 10.3.1 Information on Disposal

The device and its accessories do **not** belong in your regular household waste, since they are made of high-grade materials which can be recycled and reused. All parts must be disposed of properly by disposal facilities.

The packaging is made of environmentally friendly materials that can be used as secondary raw materials.

The consumables are designed and intended for single-use and must be disposed of after one use.

### 10.3.2 Disposal

#### Requirements

The device has been decontaminated.

- ▶ Dispose of the device. Follow the disposal instructions on our website (www.sartorius.com).
- ▶ Dispose of the packaging in accordance with local government regulations.
- ▶ Dispose of the consumables in accordance with local government regulations.

# 11 Technical Data

# 11.1 Dimensions and Weight

| Specification   | Unit | Process Filter<br>Holder | Double Process<br>Filter Holder |
|---|------|--------------------------|---------------------------------|
| Weight without cassettes  | kg   | 500                      | 950                             |
| Weight with 12 filled Sartoclear® Depth Filter cassettes and 2 manifold plates, approx. | kg   | 780                      | -                               |
| Weight with 24 filled Sartoclear® Depth Filter cassettes and 2 manifold plates, approx. | kg   | -                        | 1.430                           |
| Length × width × height   | mm   | 2300 × 925 × 905         | 2300 × 925 × 1216               |

# 11.2 Hydraulic Cylinder Dimensions

| Specification  | Unit | Value |
|--|------|-------|
| Maximum permissible stroke of the hydraulic cylinder | mm   | 290   |
| Maximum stroke of the hydraulic cylinder             | mm   | 300   |

## 11.3 Accommodation of Cassettes

| Specification   | Unit | Process Filter<br>Holder | Double Process<br>Filter Holder |
|---|------|--------------------------|---------------------------------|
| Number of Sartoclear® Depth Filter cassettes, minimum   maximum |      | 1   12                   | 1   24                          |
| Number of Sartobind® adsorption cassettes, minimum   maximum    |      | 1   On request           | 1   On request                  |
| Required number of manifold plates per level                    |      | 2                        | 2                               |

# 11.4 Ambient Conditions During Operation

| Specification  | Unit | Value     |
|--|------|-----------|
| Installation site: usually laboratory rooms, max. 2000 m above sea level   |      |           |
| Ambient temperatures in the operating temperature range  | °C   | +10 - +40 |
| Relative humidity  |      |           |
| For temperatures up to 31°C  | %    | < 80      |
| Decreasing linearly thereafter at temperatures from 31°C - 40°C  | %    | < 50      |
| Impurities   |      |           |
| Pollution degree 2 according to EN 61010 (normally only non-conductive pollution occurs. Occasionally, however, temporary conductivity caused by condensation must be expected.) |      |           |

# 11.5 Design and Lifespan

| Specification                                    | Unit  | Value |  |
|--|-------|-------|--|
| Parts exposed to the atmosphere: Stainless steel |       |       |  |
| Maximum lifespan                                 | Years | 8     |  |

# 12 Accessories

This table contains an excerpt of the accessories that can be ordered. For information on other products, please contact Sartorius.

| Accessories   | Order number |
|---|--------------|
| Dripping pan for Process Filter Holder and Double Process Filter Holder | 2ZGL0015     |
| Sartoclear® Separation Plate  | 2ZGL0013     |
| Pressure safety device  | 2ZGL0014     |

# 13 Consumables

This table contains an excerpt of the consumables that can be ordered. For information on other products, contact Sartorius.

| Accessories   | Order number |
|---|--------------|
| Sartoclear® Depth Filters   | On request   |
| Sartobind® adsorption cassettes, e.g., Sartobind® Q and S,<br>Sartobind STIC® PA, Sartobind® Phenyl | On request   |
| Inlet and outlet adapter plates (Manifold Set)  | 29Z-S00001   |
| Inlet and outlet adapter plates Gamma for Sartobind® adsorption cassettes (Manifold Set Gamma)      | 29Z-S00003   |

# 14 Sartorius Service

Sartorius Service is available for queries regarding the device. For information about the service addresses, services provided or to contact a local representative, please visit the Sartorius website (www.sartorius.com).

#### 15 Conformity

The attached documents declare the conformity of the device with the designated directives or standards.

# SARTURIUS



Original

EG-/EU-Konformitätserklärung EC / EU Declaration of Conformity

Hersteller Sartorius Stedim Systems GmbH Manufacturer 34302 Guxhagen, Germany

> erklärt in alleiniger Verantwortung, dass das Betriebsmittel declares under sole responsibility that the equipment

Geräteart Sartoclear Process Filterhalter Device type Sartoclear Process Filter Holder

Modell Model

2ZGL-0006

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinie entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Norm einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen erfüllt:

in the form as delivered fulfils all the relevant provisions of the following European Directive and meets the applicable requirements of the harmonized European Standard including any amendments valid at the time this declaration was signed listed below:

Richtlinie Directive Norm(en)

Standard(s)

Maschinen | Machines 2006/42/EG 2006/42/EC

EN ISO 12100:2010

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen: The person authorised to compile the technical file:

> Sartorius Stedim Systems GmbH **Product Compliance** 34302 Guxhagen, Germany

Sartorius Stedim Systems GmbH Guxhagen, 2022-05-20

-DocuSigned by: ariane Kindlistacher

Name des Unterzeichners: Ariane Rindlisbache Signiergrund: Ich genehmige dieses Dokument Signierzeit: 2022-08-30 | 10:17:05 MESZ

-EC96B00B56854C7684EC51AB4014C2D3

Ariane Rindlisbacher Head of Operations Guxhagen Marco Hassenpflug Name des Unterzeichners: Marco Hassenpflug

-DocuSigned by:

Signiergrund: Ich habe dieses Dokument geprüft Signierzeit: 2022-08-30 | 09:11:29 MESZ B56347BB10294B23A1BEE5E84ECA5BEC

Marco Hassenpflug Manager Quality Site

Doc: 2046813-01 SSS16CE002-01.de,en 1/1 PMF: 2046812 OP-113\_fo1\_2020.07.07





Original

# EG-/EU-Konformitätserklärung EC / EU Declaration of Conformity

Hersteller Sartorius Stedim Systems GmbH Manufacturer 34302 Guxhagen, Germany

> erklärt in alleiniger Verantwortung, dass das Betriebsmittel declares under sole responsibility that the equipment

Geräteart Sartoclear Double Process Filterhalter Device type Sartoclear Double Process Filter Holder

Modell Model

#### 2ZGL-0007

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinie entspricht und die anwendbaren

Anforderungen folgender harmonisierter Europäischer Norm einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen erfüllt:

in the form as delivered fulfils all the relevant provisions of the following European Directive and meets the applicable requirements of the harmonized European Standard including any amendments valid at the time this declaration was signed listed below:

Maschinen | Machines Richtlinie 2006/42/EG Directive 2006/42/EC

Norm(en) Standard(s)

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:

The person authorised to compile the technical file:

Sartorius Stedim Systems GmbH **Product Compliance** 34302 Guxhagen, Germany

Sartorius Stedim Systems GmbH Guxhagen, 2022-05-20

-DocuSigned by: Ariane Kindlishadur

Name des Unterzeichners: Ariane Rindlisbacher Signiergrund: Ich genehmige dieses Doki Signierzeit: 2022-08-30 | 06:40:54 MESZ

EN ISO 12100:2010

-EC96B00B56854C7684EC51AB4014C2D3

Ariane Rindlisbacher Head of Operations Guxhagen DocuSigned by

Marco Hassenpflug

Name des Unterzeichners: Marco Hassenpflug Signiergrund: Ich habe dieses Dokument geprüft Signierzeit: 2022-08-29 | 12:15:28 MESZ B56347BB10294B23A1BEE5E84ECA5BEC

Marco Hassenpflug Manager Quality Site

Doc: 2046819-01 SSS16CE003-01.de,en 1/1 PMF: 2046817 OP-113\_fo1\_2020.07.07



Original

# SARTURIUS

# **UK Declaration of Conformity**

Manufacturer Sartorius Stedim Systems GmbH

Robert-Bosch-Str. 5-7, 34302 Guxhagen, Germany declares under sole responsibility that the equipment

**Device type** Sartoclear Process Filter Holder

Model 2ZGL-0006

in the form as delivered fulfils all the relevant provisions of the following British Regulation and meets the applicable requirements of the British Designated Standard including any amendments valid at the time this declaration was signed listed below:

Machinery

Regulation

The Supply of Machinery (Safety) Regulations 2008

UK Statutory Instruments 2008 No. 1597

Standard(s)

BS EN ISO 12100:2010

#### The person authorised to compile the technical file:

Sartorius Stedim UK Ltd. Longmead Business Centre, Blenheim Road KT19 9 QQ Epsom, Surrey, UK

Sartorius Stedim Systems GmbH Guxhagen, 2022-05-20

-DocuSigned by: Ariane Kindlishadur

unane finalistaciler

Name des Unterzeichners: Ariane Rindlisbacher Signiergrund: Ich genehmige dieses Dokument Signierzeit: 2022-08-30 | 06:41:21 MESZ

Ariane Rindlisbacher Head of Operations Guxhagen —DocuSigned by:

Marco Hassenpflug

Name des Unterzeichners

Name des Unterzeichners: Marco Hassenpflug Signiergrund: Ich habe dieses Dokument geprüft Signierzeit: 2022-08-29 | 12:15:47 MESZ — B56347BB10294B23A1BEE5E84ECA5BEC

Marco Hassenpflug Manager Quality Site

Doc: 2970701-00 SS22UKCA005-00.en 1/1 PMF: 2046812 OP-113\_fo18\_2021.01.01



Original

# SARTURIUS

# **UK Declaration of Conformity**

Manufacturer Sartorius Stedim Systems GmbH

Robert-Bosch-Str. 5-7, 34302 Guxhagen, Germany declares under sole responsibility that the equipment

**Device type** Sartoclear Double Process Filter Holder

Model 2ZGL-0007

in the form as delivered fulfils all the relevant provisions of the following British Regulation and meets the applicable requirements of the British Designated Standard including any amendments valid at the time this declaration was signed listed below:

Machinery

Regulation

The Supply of Machinery (Safety) Regulations 2008

UK Statutory Instruments 2008 No. 1597

Standard(s)

BS EN ISO 12100:2010

#### The person authorised to compile the technical file:

Sartorius Stedim UK Ltd. Longmead Business Centre, Blenheim Road KT19 9 QQ Epsom, Surrey, UK

Sartorius Stedim Systems GmbH Guxhagen, 2022-05-20

-DocuSigned by:

ariane Kindlisbacher

Name des Unterzeichners: Ariane Rindlisbacher Signiergrund: Ich genehmige dieses Dokument Signierzeit: 2022-08-30 | 06:41:34 MESZ

Ariane Rindlisbacher Head of Operations Guxhagen -DocuSigned by:

Marco Hassenpflug

Name des Unterzeichners: Marco Hassenpflug Signiergrund: Ich habe dieses Dokument geprüft Signierzeit: 2022-08-29 | 12:15:57 MESZ – B56347BB10294B23A1BEE5E84ECA5BEC

Marco Hassenpflug Manager Quality Site

\_\_\_\_\_

Doc: 2970704-00 SS22UKCA006-00.en 1/1 PMF: 2046817 OP-113\_fo18\_2021.01.01

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen, Germany

Phone: +49 551 308 0 www.sartorius.com

The information and figures contained in these instructions correspond to the version date specified below.

Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.

Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

Copyright notice:

These instructions, including all components, are protected by copyright.

Any use beyond the limits of the copyright law is not permitted without our approval.

This applies in particular to reprinting, translation and editing irrespective of the type of media used.

Last updated:

10 | 2023

© 2023 Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen, Germany

HB | Publication No.: SPK6187-e231006