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## FlexAct® CH

Disposable Solution For Cell Harvest

Configurable Disposable Solutions



The FlexAct® CH is a standardized configurable disposable solution (CDS) dedicated to cell harvest steps in biopharmaceutical processes.

### Features

- Multifunctional Central Operating Module
- Configurable system configurations
- 50–1,000 L working volumes
- Quick system set-up
- Integrated single-use pressure sensor
- Controlled operation by pressure adjustment

### Benefits

- Operator friendly
- Safe handling of L-drum filters
- Fully scalable
- Efficient equipment utilization
- Enables monitoring
- Highly flexible



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## Description

The FlexAct® CH is a standardized configurable disposable solution (CDS) dedicated to cell harvest steps in biopharmaceutical processes. The FlexAct® CH addresses the entire development cycle and production capacity needs from 50 to 1.000 L for cell harvest. The integration of monitoring & control features for pressure, pump speed and fluid level control is a further milestone for the implementation of process relevant single use equipment. The integrated control allows end-users to perform other tasks during the cell harvest operation. Combined with a Palletank® and designed bag assemblies the multifunctional Central Operating Module enables the user the install, operate and monitor a fully single use unit operation.

## Components

The FlexAct® CH configurable disposable cell harvest solution consists of:

- FlexAct® COM Central Operating Module with accessories
- L-drum trolley for up to 4 L-drums for easy and safe harvest operation
- Bag assembly configurations with integrated sterilizing grade filter and a transfer set with implemented single use pressure sensor
- Weighing platforms or Palletanks® with load cells

### 1. FlexAct® COM Central Operating Module with accessories

The FlexAct® COM Central Operating Module is designed for operational excellence in cell harvest processes. It features multiple work platforms that incorporate process equipment and user friendly monitoring & control capabilities. The integrated control instrumentation together with an ergonomically positioned 10" LCD touch screen enables the operator to have an overview about the main process parameters values such pressure, pH and temperature of the Protein A eluate whilst pH adjustment, incubation, neutralization and filtration. For secure fluid level management a weight signal is provided by either load cells that are integrated into the LevMixer® Palletanks® or floor scales provided individually. The three level Central Operating Unit is able to accommodate multiple process devices required in a single-use process environment. Depending on the process needs, thermal welding and sealing provided by the BioWelder® and BioSealer® as well as filter integrity testing by using a Sartocheck® 4 integrity tester will help to quick connect and test assemblies.

#### 1.1 Sartocheck® 4

Filter Integrity Testing is an essential procedure to detect defective filter cartridges before or after use. Thus automatic integrity testers have to fulfil highest standards with respect to accuracy and reliability. At the same time the user-friendly interaction guarantees convenient handling. The Sartocheck® 4 offers solutions for all customer needs. With a comprehensive accessory package it allows highest flexibility for all integrity testing needs.

#### 1.2 BioWelder® and BioSealer®

Sterile Fusing and Sealing of thermoplastic tubing are key technologies that offer most flexibility to the end users that are interested in getting a solution for multiple connection and disconnection cycles. Sartorius' BioWelder® and BioSealer® are devices that meet these requirements set by the industry. The ability of assuring quick and reliable connections and disconnections combined with the expertise of Wave Biotech Switzerland made BioWelder® and BioSealer® to the product of choice in the biopharmaceutical industry.

## 2. Sartoclear® L-Drum Technologies

- L-drum trolley

Two different moveable L-Drum support systems are available to assure an easy and safe handling of the capsules. The 1-way system can be connected to the 4 way support system so that a capsule can be easily transferred from one system to the other.

### 3. Bag assemblies and manifold

FlexAct® CH bag assemblies and manifolds are supplied to serve the need of a fully preconfigured, ready to install, single-use unit operation. Uniquely, the transfer set and Flexel® 3D storage bags are supplied in one package. The storage bag assemblies of the FlexAct® CH configurable disposable solution are tailored to suit the dedicated need for individual mAb solution volumes at the point of use. Supplied as single Flexel® 3D bags, the FlexAct® CH storage bag assemblies provide highest flexibility and efficiency.

4. Palletanks® for intermediate mAb solution storage

The Palletank® for Storage or In-Process Handling are stainless steel container designed to perfectly fit with the Flexel® 3D LevMixer® bag assemblies.

5. Weighing platforms

The IFS4 flat-bed scales are entirely constructed of stainless steel and have an extremely low height, making it ideally suited for floor installation without a pit or anchoring. The ramp is securely attached to the scale using special retainers for prevention of force shunt. This high-quality platform can be connected to any of a wide range of indicators, for use as a Class III legal measuring instrument or without legal verification. The CIS1 Combics 1 indicator allows strain gauge weighing with flat bed scales as well as with load cells to be connected.

FlexAct® Configurator

A configurator based selection system enables the user to flexibly create the FlexAct® CH solution that meets its process requirements in cell harvest operations. All components included in the configurator are standardized components that ensure highest performance, shortest lead times and highest quality. The following Configurable Disposable Solutions will gradually complete the FlexAct family:

Unit Operation	FlexAct® Configurable Disposable Solutions
Buffer Preparation	FlexAct® BP
Virus Inactivation	FlexAct® VI
Cell Harvest	FlexAct® CH
Media Preparation	FlexAct® MP
Virus Filtration	FlexAct® VR
Ultrafiltration   Diafiltration	FlexAct® UD
Polishing	FlexAct® PO
Form & Fill	FlexAct® FF
Form & Transfer	FlexAct® FT



### Ease of Use

The primary driver behind the FlexAct® initiative is the development of disposable equipment which meets all process operations improving efficiency and speed. Sartorius Stedim specialists have analyzed the process environment and the operating procedure for cell harvest thoroughly and developed an operator friendly multifunctional Central Operating Unit. Tailored bag configurations with 30 L up to 650 L working volumes offer flexible solutions at full scalability. The system set-up is performed within minutes and needs less preparation time compared with existing solutions. Once the operation is performed, the system can be as fast rigged-off without the needs of tedious cleaning requirements. Set-up and rig-off ease allow for more efficient and faster equipment utilization adding to the overall process capacities. The monitoring on a 10" touch screen of all main process parameter is easily enabled by integrated disposable sensors.

### Validation

Flexel® 3D bags have been qualified applying the most stringent and current test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® 3D bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single use products with a sterility assurance level of  $10^{-6}$  over the shelf life.

Flexel® 3D bags are tested for compliance to:

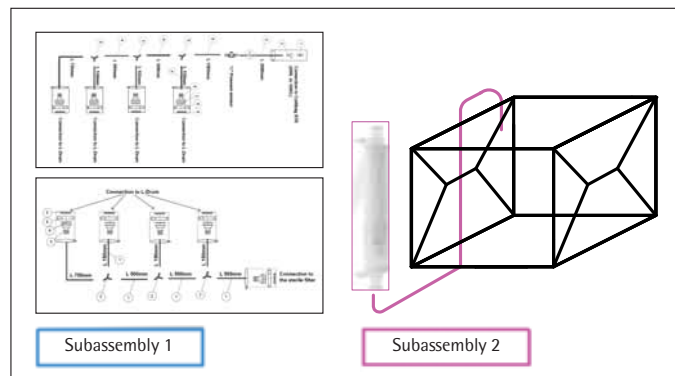
- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19: Particulate
- ISO 11737: Bioburden
- ISO 11137: Sterilization of Medical Devices

### Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

### Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes and state-of-the-art utilities. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a flexible and robust supply chain that can cope with strong market growth.



The schematic above shows the bag assemblies connected



## Specifications

### 1. FlexAct® CH Central Operating Module

Material:	316 L Stainless Steel
Surface Finish:	Optional: – Powder coated   coloured – Glass Bead Blasted, electropolished
Dimensions (W × D × H):	795 × 1410 × 1500 mm (31.3 × 55.51 × 59.06 inch)
Weight (approx.):	160 kg (352.74 lbs) (incl. Watson Marlow pump)
Control Unit:	– Control unit with 10.4" touch screen



## Pump

Watson Marlow	720UN   R
Specification:	IP66 0.1 – 360 rpm
Pumphead:	720R pumphead, 4 roller pumphead for maximum 2 bar. Accepts continuous tubing only (includes continuous tube clamp set)

### BioWelder®

Power requirements:	100–240 V   47–63 Hz
Dimensions:	300 × 300 × 220 mm
Weight:	0.5 kg
Housing:	stainless steel
Interface:	RS232 for printer
Blade:	Cr-Ni-Alloy, single-use
Ambient temperature:	20°C–30°C (ideal: 22°C)
Relative Humidity:	20%–80% (ideal: 60%)
Temperature Sensor:	Type K, calibration holder available
Max. Tube OD:	3/4"
Min. Tube OD:	1/4"
Welding Cycle:	60–90 sec. depending on tube dimension
Standard settings for:	C-Flex®, PHARMED® BPT, Sanipure® 60



### BioSealer®

Power requirements:	100–240 V   47–63 Hz
Dimensions:	220 × 150 × 210 mm
Weight:	3.0 kg
Housing:	stainless steel
Compression head:	Aluminum anodised
Ambient temperature:	20°C–30°C
Relative Humidity:	35%–65%
Max. Tube OD:	3/4"
Min. Tube OD:	1/4"
Sealing Cycle:	1–4 minutes depending on tube size and quality
Tubing Types:	Soft Thermoplastic Tubing, (e.g. C-Flex®, SaniPure® 60 and Pharmed® BPT)







### Sartochek® 4 plus

Power requirements: 100 – 240 V AC, 50 | 60 Hz

Maximum power input: 74 watts

Maximum operating pressure: 9999 mbar | 145 psi

Minimum inlet pressure: 4000 mbar | 58 psi

Dimensions  
(W × D × H1 × H2): 460 × 390 × 140 × 245

### Measuring ranges:

Test pressure 100 – 8000 mbar | 1.5 – 116 psi

Pressure drop 1 – 2000 mbar | 0.01 – 29 psi

System inlet volume  
– with internal ref. Vessel 14 L  
– with external ref. Vessel max. 150 L

### Measuring accuracy:

Pressure ± 0.1% full scale

Pressure drop ± 1 mbar | 0.015 psi

Volume determination ± 4%

Diffusion ± 5%

Water-Intrusion ± 5%

Bubble Point ± 50 mbar | ± 0.7 psi

### Operating conditions:

Ambient temperature +15°C to +35°C

Rel. humidity 10 – 80%

### Touch Screen:

Size 10.4" TFT

Features 256 colors

### Communication Ports:

Serial Port TU RS232

Serial Port MU RS485

PLC Port binary signals 12 pins

Network RJ45

### Language option:

English  
German  
French  
Spanish  
Italian



- 1: ext. reference tank
- 2: Venting 1
- 3: Out
- 4: Venting 2
- 5: Compressed Air In
- A: external sensor
- B: external valves



- 1: main switch
- 2: SD card reader
- 3: Serial Port TU
- 4: PLC Port
- 5: RJ45 Network
- 6: connection for optional barcode scanner



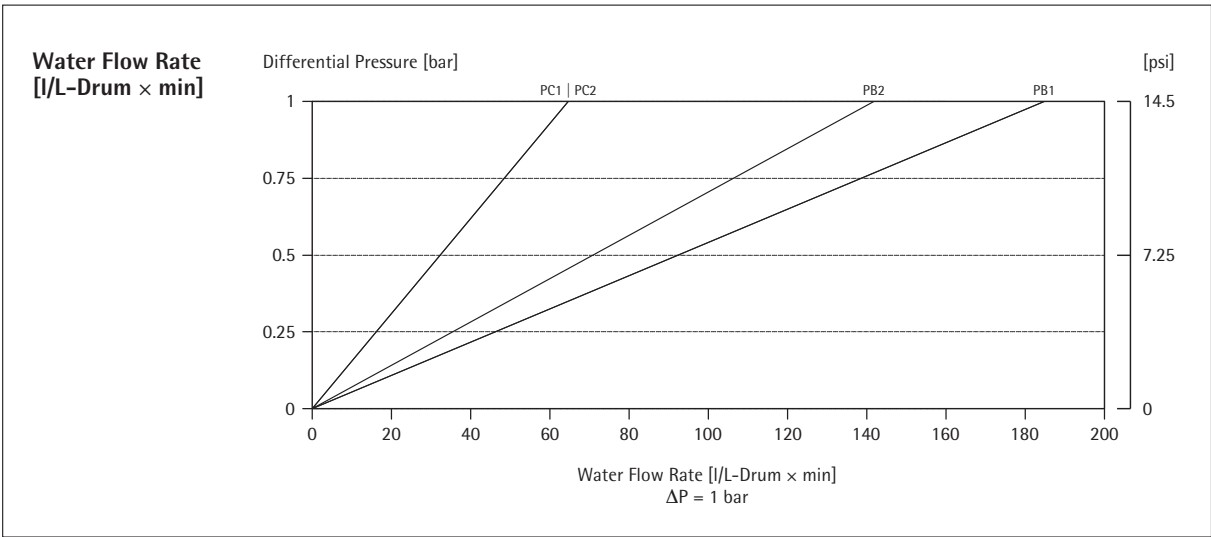
2. L-drum technologies

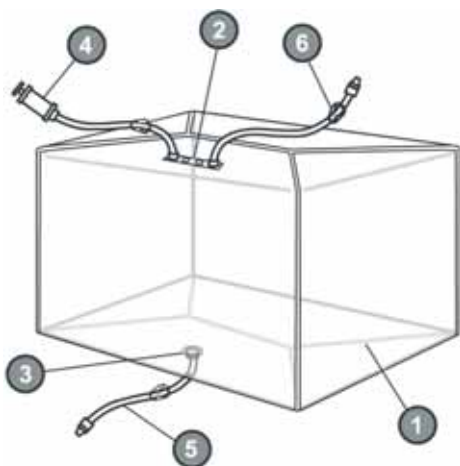
2.1 L-drum trolley  
Two different moveable L-Drum support systems are available to assure an easy and safe handling of the capsules. The 1-way system can be connected to the 4 way support system so that a capsule can be easily transferred from one system to the other. Customized support systems can be made on request.

	1-way support system	4-way support system
Length	38 cm	71 cm
Width	57 cm	70 cm
Height	122 cm	130 cm
Weight	24 kg	52 kg

2.2 Sartoclear® L-drums  
Sartoclear® P L-Drums are cellulose based depth filters, especially developed for use in the Biopharmaceutical industry. The depth filter media provide a combined clarification effect by both, size exclusion and adsorptive mechanisms. The Sartoclear® P L-Drum is the first production scale disposable depth filter line, without the need for expensive clamping systems. The "Plug and Play" filter capsules reduce the set up time to a minimum and provide 100% disposability of all fluid contacting components.

Filtration volumes  
Sartoclear® P L-Drum are used for the filtration of 100 L up to 600 L per module, depending on the application. The required filtration area needs to be confirmed by small scale tests using Sartoclear® P MaxiCaps®.





### 3. FlexAct® CH – Bag assemblies and transfer sets

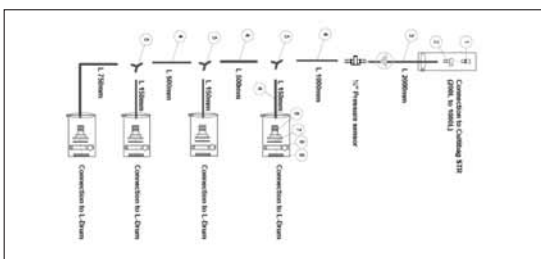
#### 3.1 Flexel® 3D Bioprocessing Bag for Storage

Bag Chamber:	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Tubing material:	C-Flex®, Silicone
Number of Ports:	2 top ports, 1 bottom port
Filter:	Sartopore® 2 gamma MidiCaps®   MaxiCaps®
Fittings:	Tri-clamp, Luer Lock female female with needle free sampling port
Volumes:	50 L, 100 L, 200 L, 500 L, 1000 L
Sterilization:	by Gamma Irradiation

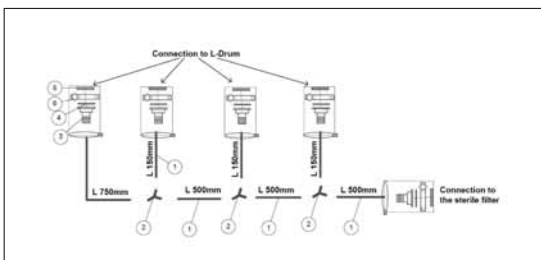
#### 3.2. FlexAct® CH – Transfer set

##### 3.2.1 Transfer set for CultiBag STR 50

- Transfer set FlexAct® CH (to be connected with outlet port MPC male of the CultiBag STR 50)
- MPC 3/8" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2"(hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)
- Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP
- Outlet with gasket, clamp and cap. (see picture b)



Picture a)



Picture b)

##### 3.2.2. Transfer set for CultiBag STR 100-1000

- MPX 1/2" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2"(hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)
- Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP
- Outlet with gasket, clamp and cap (see picture b)

## 4. Palletank®

### 4.1 Palletank® for Storage

Material:	304 L Stainless Steel
Surface Finish:	Glass Bead Blasted
Stackable:	3 (50-200 L) 2 (500 L)
Option:	Dolly

Volume (L)	Dimensions (W × D × H)	Weight (kg) Palletank®
50 L	490 × 490 × 750	24
100   200 L	789 × 592 × 891	35
500 L	1192 × 792 × 1010	92
1,000	1260 × 1060 × 1443	145



## 5. Weighing platforms – IFS flat-bed scales

### 5.1 IFS4-300LI-I

Weighing capacity:	300 kg
Platform size:	1000 × 800
Height:	standard
Load plate:	AISI304/1.4301V2A bead-blasted
Resolution:	30.000 d
Readability:	10 g



### 5.2 IFS4-1500NN-I

Weighing capacity:	1,500 kg
Platform size:	1250 × 1250
Height:	standard
Load plate:	AISI304/1.4301V2A bead-blasted
Resolution:	30.000 d
Readability:	50 g

### 5.3 Combics CIS1 – Scale Indicator

Indicators for complex weighing tasks in 4 different versions.

Max. readability:	31.250 digits
IP protection rate:	IP67 (PG cable gland), IP44 (25-pol. D-SUB), (IP65 as option)



## Ordering information

### 1. FlexAct® Central Operating Module

Part Number	Description
4SZZNL201	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel EU 230 V, st.steel version
4SZZNL501	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel US 110 V, st.steel version
4SZZNL202	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel EU 230 V, powder coated version
4SZZNL502	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel US 110 V, powder coated version

### 2. L-drum technologies

#### 2.1 L-drum trolleys

##### Order number

2ZGB--0001	Trolley for 4 L-Drums, 70 cm × 70 cm × 120 cm (l × b × h)
2ZGB--0002	Trolley for 1 L-Drum, 70 cm × 70 cm × 120 cm (l × b × h)

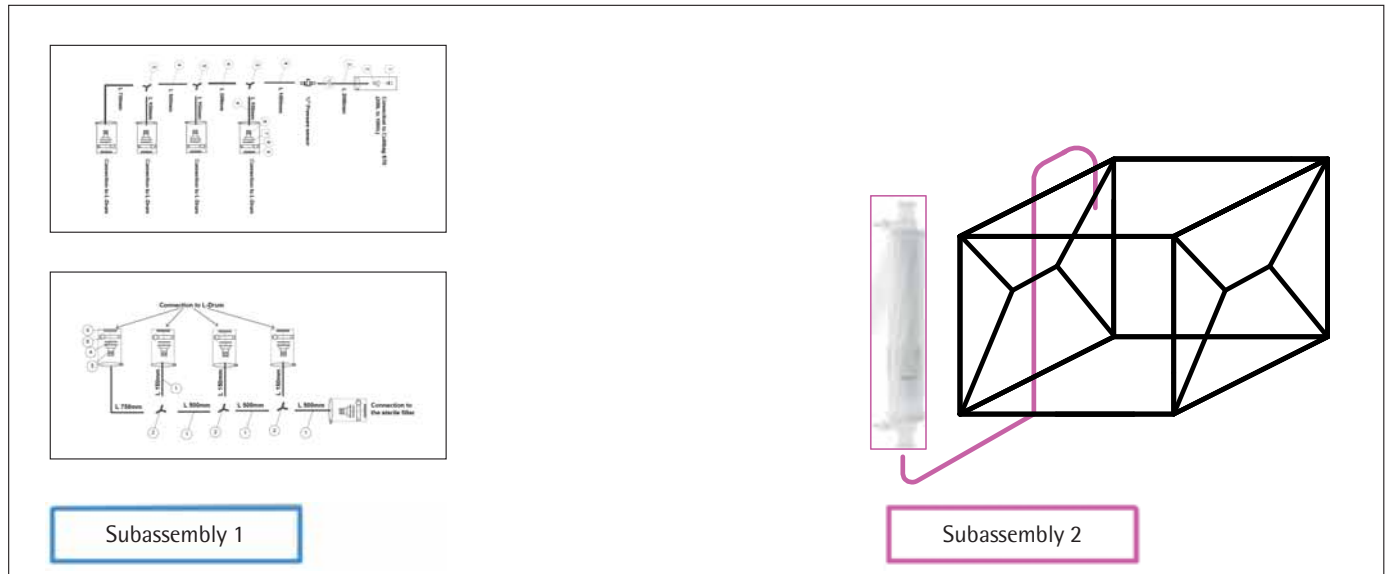
#### 2.2 Sartoclear® L-drums

Order number	Grade	Retention Rating	Application
295PB1P13ALSS	PB1	11 µm   4 µm	High Cell density (>107/ml) Post Bioreactor*
295PB2P13ALSS	PB2	8 µm   1 µm	Common Cell density (<107/ml) Post Bioreactor*
295PC1P13ALSS	PC1	1.0 µm   0.3 µm	Particle containing Post Centrifuge applications, 100–150 FNU*
295PC2P13ALSS	PC2	0.3 µm   0.3 µm	Post Centrifuge applications, <100 FNU*

\* Value is an indication, the choice of media should be based on small scale tests.

### 3. Disposable Bag Assemblies

#### Legend:



Part Number	Subassembly 1	Subassembly 2
4CH-----14AA10502	Transfer set FlexAct® CH (to be connected with outlet port MPC male of the CultiBag STR 50) <sup>1</sup>	50 L Flexel® 3-D bag with Sartopore® 2 Gamma height 7
4CH-----15AB11003	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 - 1000) <sup>2</sup>	100 L Flexel® 3-D bag with Sartopore® 2 Gamma height 8
4CH-----15AC12004	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 - 1000) <sup>2</sup>	200 L Flexel® 3-D bag with Sartopore® 2 Gamma height 9
4CH-----15AD15005	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 - 1000) <sup>2</sup>	500 L Flexel® 3-D bag with Sartopore® 2 Gamma MaxiCaps® 10"
4CH-----15AD11T06	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 - 1000) <sup>2</sup>	1000 L Flexel® 3-D bag with Sartopore® 2 Gamma MaxiCaps® 20"

<sup>1</sup> MPC 3/8" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2" (hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)  
Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP  
Outlet with gasket, clamp and cap.

<sup>2</sup> MPX 1/2" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2"(hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)  
Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP  
Outlet with gasket, clamp and cap (see picture b)

#### 4. Palletank for storage (50–1000 L) | in-process handling (1000 L)

Order Number	Palletank
FXC113946	Palletank® 50 L for storage stackable
FXA113988	Dolly for Palletank® 50 L (storage)
FXC110733	Palletank® 100 L for storage stackable
FXS102254	Dolly for Palletank® 100 L   200 L (storage & shipping)
FXC110733	Palletank® 200 L for storage stackable
FXS102254	Dolly for Palletank® 100 L   200 L (storage & shipping)
FXC110734	Palletank® 500 L for storage stackable
FXC100734	Dolly for Palletank® 500 L (storage & shipping)
FXC106223	Palletank® 1000 L for in-process fluid handling
FXS102259	Dolly for Palletank® 1000 L for in-Process fluid handling

#### 5. Weighing Platforms

##### 5.1 Floor Scales (Flat bed scales)

Part Number	Platform dimensions (mm)	Weighing capacity	Readability	Load plate	Dust   water protection
IFS4-300LI-I floor scale (flat bed scale)	1000 × 800	300 kg	10 g	AISI304/1.4301 V2A bead-blasted	IP67   IP68
IFS4-1500NN-I floor scale (flat bed scale)	1250 × 1250	1500 kg	50 g	AISI304/1.4301 V2A bead-blasted	IP67   IP68

##### 5.2 Combics CIS1 – Scale indicator

Combics 1 scale indicator, stainless steel housing, IP44	CISL1
Combics 1 plus scale indicator, stainless steel housing, IP44	CISL1N
Combics 2 scale indicator, stainless steel housing, IP44	CISL2
Combics 3 scale indicator, stainless steel housing, IP44	CISL3
Combics 1 scale indicator, stainless steel housing, IP67	CIS1
Combics 1 plus scale indicator, stainless steel housing, IP67	CIS1N
Combics 2 scale indicator, stainless steel housing, IP67	CIS2
Combics 3 scale indicator, stainless steel housing, IP67	CIS3

##### Optional interfaces (UniCOM)

Interface module (RS-232C)	YD001C-232
Interface module (RS-485   422)	YD001C-485
Analog current output, 0–20 mA, 4–20 mA, 0–5 V, 16-bit	YDA01C-20MA
Profibus module	VD001C-DP
Bluetooth® module (only for CIS models)	YD001C-BT

##### Replace A | D converter (WP1) with a digital interface

Interface (RS-232   485) for direct connection of a digital platform	YDI01C-WP
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### Printers and printer accessories

with functions for date, time and statistical evaluations	YDP03-OCE
Printer paper (5 rolls; length per roll: 50 m)	6906937
Replacement ink ribbon cartridge for printer	6906918
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 108 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator; only for use with flexible printout configuration (see "Software," next column)	YDP12IS-OCEUV
Printer paper (1 roll) for YDP12IS-OCE printer, 101 mm × 75 m, thermal sensitive paper	69Y03196
Labels for YDP12IS-OCE printer, extra large, 101 mm × 127 m, 305 labels	69Y03195
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 60 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator (see "Software," next column)	YDP04IS-OCEUV
Printer paper (3 rolls) for YDP12   04IS-OCE, 60 mm × 75 m, thermal sensitive paper	69Y03090
Labels for YDP12   04IS-OCE printer, small, 58 mm × 30 mm, 1000 labels	69Y03092
Labels for YDP12   04IS-OCE printer, medium, 58 mm × 76 mm, 500 labels	69Y03093
Labels for YDP12   04IS-OCE printer, large, 58 mm × 100 mm, 350 labels	69Y03094
Cable for direct connection of YDP12IS   YDP04IS-OCE printer to Combics CISL indicators	YCC01-01CISLM3

### Electrical accessories

External red   green   red display for Combics CISL indicators	YRD11Z
External red   green   red display for CIS indicators (12-pin round connector); connecting cable YCC02-R12F6 or Option M6 required	YRD14Z
Profibus connector for CISL... and CW...P... indicators (D-SUB 25-   9-pin)	IE10092
Second display for Combics CISL indicators	YRD02Z
Remote display, 7-segment, up to 45 mm characters	Information available on request
Bar code scanner, with cable for connection to Combics CISL scale indicator adapter cable, 120 mm scanning width	YBR02CISL
Bar code scanner for the Combics CIS model, with connecting cable, for connection with YCC02-R12F6	YBR02FC
Foot switch, incl. T-connector, D-SUB 25-pin	YFS01
Hand switch, incl. T-connector, D-SUB 25-pin	YHS02
External Alibi memory for electronic storage of weighing data	YAM01IS
Scanner for loading weighing data from YAM13IS Alibi memory cards to a PC	YAM02IS
Power supply for YAM01IS or YAM02IS Alibi memory	YAM11IS
Memory card for YAM01IS Alibi memory	YAM13IS
Cable for connecting Combics indicator to YAM01IS Alibi memory, 25-pin D-SUB to 9-pin D-SUB, 25 pol. D-SUB auf 9 pol. D-SUB	YCC01-10CIM3
Cable (D-SUB 9-pin, 2 m) for connecting YAM01IS Alibi memory to a PC	69EM0012
Flow rate controller for pumps with analog or digital pulse interface	YFC02Z-V2



### Mechanical accessories

Installation kit for pit frame installation (disconnectable plug-in cable for indicator)	YAS99I
Wall-mounting bracket, stainless steel	YDH01CIS
Wall-mounting bracket, stainless steel, tiltable	YDH02CIS
Floor-mounted column	YDH03CIP
Floor-mounted column, stainless steel	YDH03CIS
Base for installing floor-mounted column, stainless steel	YBP03CIS
Retainer for bar code scanner, for attachment to floor-mounted column, bench column or complete scale column	YBH01CWS
Plate for attaching printer to floor-mounted column or bench column	YPP01CWS

### Software

Flexible printout configuration (e.g., bar codes, variable font sizes, embedding graphics, and similar) – Just ask your sales consultant

Sartorius WinScale driver software for Windows® 95   98   2000   NT with current display of the weights and verifiable PC data memory, RS-232C, connecting cable 7357314 required	YSW03
SartoCollect software for the data communication between PC and any Sartorius instrument (incl. cable 26 Pin, 2 m)	YSC02

### Power supplies

24-V industrial power supply module	YAS02CI
External rechargeable battery pack, operates up to 40 hours, incl. battery charger	YRB10Z
External rechargeable battery pack, operates up to 40 hours, battery charger not included	YRB10Z-R
Connecting cable (25-pin, D-SUB) for YRB10Z rechargeable battery pack, 2 m	YCC02-RB01
Connecting cable with cable gland for YRB10Z rechargeable battery pack, 2 m*	YCC02-RB02
Connecting cable with cable gland, for car battery, 2 m*	YCC02-CB02

\* only for CIS 1 | 2 | 3 indicator

### Connecting cables

with cable gland for YBR02FC bar code scanner*	YCC02-BR02
with cable gland for D09F6 printer, 9-pin D-SUB male connector, 6 m*	YCC02-D09M6
with cable gland for accessories, 9-contact D-SUB female connector, 6 m*	YCC02-D09F6
with cable gland for Sartorius scale, 25-contact D-SUB female connector, 1.5 m*	YCC02-D25F6
with cable gland for Sartorius scale, 25-pin D-SUB male connector, 6 m	YCC02-D25M6
with cable gland for accessories or IS platform, 12-pin round male connector, 6 m*	YCC02-R12M6
with cable gland, 12-contact round female connector, 1.5 m*	YCC02-R12F6
Cable for YDA01C-20MA power interface, with open cable ends e.g., 5 + = 5 m	6906926
Cable for connecting a PC, 25-pin, D-SUB, 1.5 m	7357312
Cable for connecting a PC, 9-pin, D-SUB, 1.5 m	7357314
Cable for connecting isi, QA   QC, FB   FC scales (25-pin D-SUB male connector to 12-pin round male connector), 3 m	YCC01-02ISM3
Connecting cable for scales, 25-contact D-SUB male connector (25-pin D-SUB female connector to 25-pin D-SUB male connector), 3 m	YCCDI-01M3
Connecting cable for scales to IS platform (25-pin D-SUB male connector to 12-contact round female connector), 3 m	YCC01-03CISLM3
Cable for connecting scale to platform, junction box or other weighing system equipment, approx. 8 mm outer diameter, shielded, with open ends; e.g., 5 + = 5 m	69Y01100

### Other accessories

In-use covers (set of 2)	YDC01CI
IP65 upgrade kit for the IP44 protected Combics CISL indicators	YAS01CISL
Anti-theft locking device	YTP01CI
Cable gland for Combics model CIS, IP67 protected*	YAS04CIS
Installation kit for integration in a control panel	YAS03CI

\* only for CIS 1 | 2 | 3 indicator

## 6. Accessories

### 6.1 Sartocheck® 4 plus

Order Number	Order Code Description
26288	Sartocheck® 4 plus (following items included)
18104	Inlet tubing for compressed gas (included)
18103	Outlet tubing for compressed gas (included)
6982141	Ribbon cassette (included)
6982142	Rolls of printer paper (included) Test certificate (included) Calibration certificate (included) Installation and operating instructions (included)
16288---VP	Validation package Power cord (country specific)
Order Number	Accessories Sartocheck® 4 plus
26288---BS	Barcode Scanner
16288---TU	Multunit
1ZE---0018	External pressure transducer
1ZE---0025	Set for external venting (1 valve)
1ZE---0026	Valve set for external filling (WIT) Serial Port Interface cable TU   TU
1ZE---0008	0.5 m
1ZE---0009	2 m
1ZE---0010	5 m Network Cable
1ZE---0029	2 m
1ZE---0030	5 m
1ZE---0031	10 m
1ZE---0032	20 m
26288---CK	Cleaning Kit
26288---PV	Pressure Tank for Cleaning
16288---RV	External reference vessel (10 L)
16288---PI	Profibus Interface
26288---VP	Validation Package
1ZE---0021	Clean Room Venting Adapter
1Z-LB-0002	Midisart Test Manifold 10

## 6.2 BioWelder®

Order Number	Order Code Description
16370	BioWelder®, Fully automated tube fusing unit
16372	Citizen Printer Print cable, AC adapter, paper roll and ribbon cassette
16373	Disposable Cutting Blades, with laser point 0.4 mm, 50 pcs./package,
16374	Calibration Kit With specifically designed holder, integrated temperature sensor type K and coding for calibration program recognition, calibration document for sensor included
16384	4-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16385	4-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16386	4-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16375	2-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16376	2-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16377	2-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16378	2-fould Tube Holder OD 7/16" (11.1 mm), ID 5/16" (8.0 mm) Wall 1/16" (1.6 mm)
16379	2-fould Tube Holder OD 1/2" (12.7 mm), ID 3/8" (9.5 mm), Wall 1/16" (1.6 mm)
16380	2-fould Tube Holder OD 5/8" (15.9 mm), ID 3/8" (9.5 mm), Wall 1/8" (3.2 mm)
16381	2-fould Tube Holder OD 3/4" (19 mm), ID 1/2" (12.7 mm), Wall 1/8" (3.2 mm)

### 6.3 BioSealer®

Order Number	Order Code Description
16360-P1	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"-1" and wall thickness 1/16" – 3/32" Optional Parametersets: 1–6**
16360-P2	
16360-P3	
16360-P4	
16360-P5	
16360-P6	
16361-P1	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"-1" and wall thickness 1/16" – 3/32" Equipped with a removable Sealing Head Optional Parametersets: 1–6**
16361-P2	
16361-P3	
16361-P4	
16361-P5	
16361-P6	
16362-P7	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Optional Parametersets: 7–12**
16362-P8	
16362-P9	
16362-P10	
16362-P11	
16362-P12	
16363-P7	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Equipped with a removable Sealing Head Optional Parametersets: 7–12**
16363-P8	
16363-P9	
16363-P10	
16363-P11	
16363-P12	
16365	IR Interface incl. Software CD
16366	Ceramic Heating Element Type 1 specified for BioSealer® 16360–16363

\*\* The definition of each parameterset can be obtained in the parametersheet

## 7. Validation

CONFIDENCE®: Product and Process Specific Validation Services

Sartorius Stedim Biotech Validation Services conducts testing according to current regulatory requirements and guidance documents used in the industry such as PDA Technical Report No. 26 "Sterilizing Filtration of Liquids".

Testing is offered for filter elements, bags and other polymer-based components such as tubing, gaskets, stoppers, vials etc. Considering the process conditions, product formulation and process steps, the test scope (type of test, number of test filter elements or other test components) and complexity of the studies can vary.

Article No.	Description
861096	Validation protocol including one revision.

### Microbiological Studies

861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria <i>Brevundimonas diminuta</i>
861015	Viability Test for determination of the bactericidal nature of the product (non-standard)
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria <i>Brevundimonas diminuta</i>

Bacteria Challenge Test performed with 3 filter elements from different lots

861012	Bacteria Challenge Test using the standard test bacteria <i>Brevundimonas diminuta</i>
861016	Bacteria Challenge Test (non-standard)

### Determination of Product Specific Integrity Test Limits

Product Integrity Test performed with minimum 3 filter elements from different lots

861020	Determination of product specific integrity test limits
862021	Determination of product specific integrity test limits (non-standard)

### Chemical Compatibility Studies

Chemical Compatibility Test performed with 3 filter sets from different lots

861022	Chemical Compatibility Test
861024	Chemical Compatibility Test (non-standard)

### Adsorption Studies (upon request)

### Particle Release Studies

Particle Release Test typically includes 3 filter elements from different lots

861031	Particle Release Test
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Leachables | Extractables Studies (analysis of drug product formulation usually requires sample preparation)

Extraction procedure always includes a blank, customer to decide on  
1 or 3 filters | bags | components for extraction

861040	Static Extraction (out of box, without prior treatment)
861041	Extraction (including sterilization and   or flushing)
861044	Extraction (non-standard)

Two pretests may be required for complex products, e.g. formulation buffer and complete solution

861070	Analytical pre-test to identify product interference
861071	Analytical pre-test with sample preparation

Number of analyses normally reflects number of extract samples, including blank

861047	GC-MS Analysis without sample preparation
861048	GC-MS analysis with sample preparation
861051	HPLC analysis without sample preparation
861052	HPLC analysis with sample preparation

Following a standard approach HPLC and GC-MS are typical methods for the initial leachables analysis. If no peaks are detected no further study is performed. Additional analysis and type of analytical methods depend on the amount of peaks detected and their signal intensity. A suitable analytical scheme is then developed in a second step case by case.





Flexel® for LevMixer® bag, using ATMI patented mixing technology

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