



FlexAct® UD

Single use Solution for Ultrafiltration & Diafiltration

Configurable Disposable Solutions



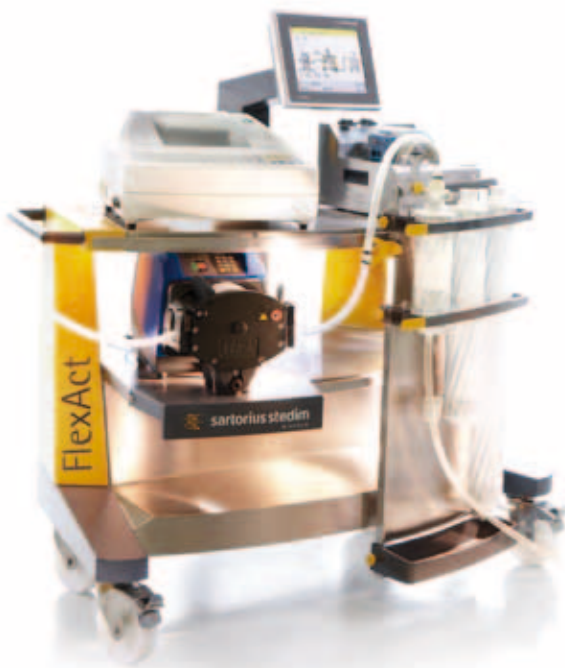
The FlexAct® UD combines innovative Single use technology with Crossflow filtration performance for ultrafiltration and diafiltration (UD) applications used in many downstream processes.

Features

- Multifunctional Central Operating Module
- Single use ultrafiltration processing with encapsulated pre-sterilized assembly
- Pre-flushed & sterile Hydrosart® inside
- 50 – 500 L process volume
- Quick system set-up
- Integrated single-use pressure sensor
- Controlled operation by pressure adjustment

Benefits

- Speed up your processes
- Saves substantial quantities of WFI
- Operator friendly
- Optimized for sheer-sensitive products
- Efficient equipment utilization
- Easy to assemble via Opta® sterile connectors
- Highly flexible



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Description

The FlexAct® UD combines innovative Single use technology with Crossflow filtration performance. Bag Loop assemblies for FlexAct® UD are supplied sterile and ready to use. Each assembly is optimized for ultrafiltration and diafiltration (UD) applications used in many downstream processes like purification of vaccines, monoclonal antibodies or recombinant proteins. All product wetted parts of the System are supplied sterile and made from Single use components. The system is suitable for use in cGMP environments for process development, clinical trials and for small-scale production batches. The system is an ideal choice for Contract Manufacturers, research and development applications and all companies with multiproduct through-put.

The Central Operating Module (COM) of FlexAct® UD is equipped with a gamma pre-sterilized loop consisting of a Self Contained Hydrosart UF – Sartocube®, single-use pump head, pressure domes, bag and tubing. This Crossflow System is equipped with our DCU4 control unit that can communicate with Sartorius Stedim Biotech's SCADA, MFCS software. The Crossflow filter holder is specially designed for Sartorius' Self Contained Sartocube® with a membrane area of 3.5 m². The unit and its touch screen are splash-proof and can withstand continuous use in both laboratory and production conditions. The system is easy to install in the production area.

Components

1. FlexAct® UD COM (Central Operating Module) with accessories

The FlexAct® UD COM is equipped with a Sartacon® hydraulic holder for Self Contained Sartocube® operation, two pressure transmitters, overpressure protection and a 4 - piston membrane pump for sheer sensitive products (1.1 m³/h vs. 2 bar). One peristaltic feed pump is integrated to load product or buffer as discrete process steps.

The FlexAct® UD COM is designed for operational excellence in all downstream processes. It features multiple work platforms that incorporate process equipment and user friendly monitoring & control capabilities. The integrated DCU4 control together with an ergonomically positioned 10,4" LCD touch screen enables the operator to have an overview about the main process parameters values. For secure fluid level management a weight signal is provided by either load cells that are integrated into the Pallettanks® or floor scales provided individually.

1.1 FlexAct® UD

is optimized to be connected to a Flexel® 3D Bag for Magnetic Mixer in configuration of 50 L volume.

1.2 Palletank®

for Magnetic Mixing – These stainless steel containers are designed to perfectly fit with the Flexel® 3D bags and include a railed port interface for the coupling of the mobile Drive Unit.

1.3 Magnetic Drive Unit –

Magnetic Mixer Drive Unit generates the rotation of the single-use magnetic impeller coupled to a non-shedding ceramic bearing. The Magnetic Mixer Drive Unit is mobile, cart-mounted and designed to interface with Palletank® for Magnetic Mixer of different volumes.

2. 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.

3. Bag Loop with Self Contained Sartocube® – Hydrosart inside

For Single Use processing FlexAct® UD is supplied with a gamma sterilized loop consisting of a pre-flushed Hydrosart Self Contained Sartocube®, two pressure domes and a 50 L recirculation bag with vent filter and tubing. The Self Contained Sartocube® with 3.5 m² membrane area – available with a MWCO of 10 kDa and 30 kDa – is integral part of the gamma sterilized loop assembly. The system is suitable for use in laboratory and cGMP environments.

OPTA® sterile connectors with colored tags – eases the connectivity to the bag loop while maintaining the sterile envelope. The Single use pressure domes are located in feed and retentate line and simply snapped on to the reusable pressure transducer.

4. 50 L Recirculation Bag – Flexel® for Magnetic Mixer

Flexel® for Magnetic Mixer is a single-use, high performance mixing solution. The system consists of three separate components designed to fit together to offer a maximum process flexibility.

1.1 FlexAct® UD is supplied with a Flexel® 3D Bag for Magnetic Mixer in configuration of 50 L volume.

1.2 Palletank® for Magnetic Mixing – These stainless steel containers are designed to perfectly fit with the Flexel® 3D bags and include a railed port interface for the coupling of the mobile Drive Unit.

1.3 Magnetic Drive Unit – Magnetic Mixer Drive Unit generates the rotation of the single-use magnetic impeller coupled to a non-shedding ceramic bearing. The Magnetic Mixer Drive Unit is mobile, cart-mounted and designed to interface with Palletank® for Magnetic Mixer of different volumes.

2. 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.

5. Control Unit

All control and alarm functions are set and displayed on the 10.4" touch screen. The screen displays all signal readouts, set point controllers and trend curves to ensure user friendly operation. It enables immediate process control even when you change parameters on the fly. Active controllers and alarms are visualized in the main display.

The optional logbook function stores alarms, set points and user logs. All logbook entries are transferable to the optional MFCS/win SCADA software and can be personalized with three-level password protection.

6. Process Sequences

Predefined sequences provide operation for membrane conditioning, Concentration, Diafiltration (UF | DF) and Rinsing using predefined parameters.

All FlexAct® COM units are equipped with a feed pressure and level controllers for running the system at user defined set points. The feed pressure controller keeps the feed pressure constant by controlling the pump speed (feed pressure is the defined value). Delta P and the retentate flow can be influenced by feed pressure and adjustment of the retentate valve.

The level controller can run one integrated peristaltic pump to keep the volume in the recirculation bag constant.

7. Data Acquisition

Data are collected using an external PC (not part of the equipment supplied) connected to the FlexAct® UD system over an Ethernet interface. SCADA MFCS software for data acquisition, batch management and visualization is included in the FlexAct® UD package. In addition, you can easily integrate this system into existing MFCS networks with Sartorius Stedim Biotech bioreactors or fermentors and incubation shakers.

8. cGMP Production Environment

Optionally, validated MFCS/win software can be upgraded with our 21 CFR Part 11 and S88 recipe option. The BioPAT® MFCS/win OPC specifies the communication of real – time data between control devices from different manufacturers. This convenient option offers you the possibility of connecting the FlexAct® UD to Delta V.

FlexAct® Configurator

A configurator based selection system enables the user to create the FlexAct® UD solution that meets its process requirements in ultrafiltration | diafiltration 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
Formulation & Fill	FlexAct® FF
Formulation & Transfer	FlexAct® FT
Multi-fill system	FlexAct® MF



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. 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 single use 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.



Technical Specifications

Bag Loop Assembly

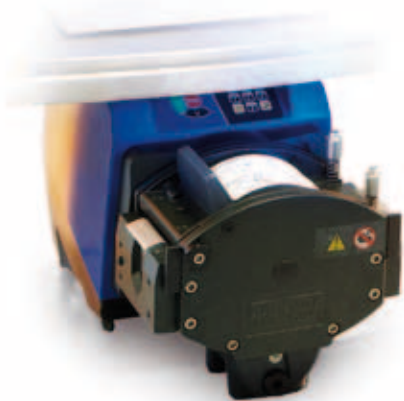
Filter	Self Contained Sartocube® - 3.5 m ² Hydrosart (MWCO 10kDa, 30 kDa)
Max. inlet pressure	2 bar (29 psi)
Recirculation bag	Flexel® 3D Bag for Magnetic Mixer in configuration of 50 L volume
Connections	Opta®

FlexAct® UD COM

Material	316 L Stainless Steel
Surface Finish	Optional: Powder coated coloured Glass Bead Blasted, electro polished
Dimensions (W × D × H)	795 × 1410 × 1500 mm (31,30 × 55,51 × 59,06 inch)
Recirculation Pump output	4-piston membrane pump 1100 l/h@2 bar (29 psi)
Weight (approx.)	160 kg (352,74 lbs) (incl. peristaltic pump)
Control Unit	DCU4 with 10,4" touch panel
Electrical requirements	230 VAC/50 Hz, 115 VAC/60 Hz

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)



Recirculation module

Magnetic Mixer Drive Unit

Electrical requirements	Single Phase 230 V, 50/60 Hz - 110 V, 60 Hz Japan Single Phase 230 V, Transformer (110 V Input), 50/60 Hz
Dimensions (W × D × H)	410 × 840 × 1040 mm (16 × 33 × 41 inch)
Weight	25 kg (55 lb)
Impeller Speed	0 - 300 rpm
Ambient Temperature	4° to 30°C
Max. Humidity	85% (non-condensing), avoid condensation, for indoor use
Mobility	Mounted on stainless cart with four clean room wheels and push handle
IP Rating	NEMA 4X, IP 65
Vessel Changeover	< 7 Minutes



Palletank® for Magnetic Mixer with or without load cells

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Door	Front Hinged Door
Windows	Plexiglas
Ports	Railed port for drive unit Front bottom port for bag line access
Volume	50 L
Dimensions (W × D × H)	825 × 570 × 1,051
Weight	43 kg

Options

Palletank® for Storage

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

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
1000 L	1260 × 1060 × 1443	145

To connect the storage bag to the permeate outlet of the bag assembly one can use our BioWelder®; for disconnection the BioSealer®.





Weighing platforms – IFS flat-bed scales

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

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

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)

Optional Software

MFCS/win Standard software package
Recipe Control (S88) software module
21 CFR part 11 software module
BioPAT® MFCS/win OPC

Ordering Information

Available types and order numbers

FlexAct® UD COM – Central Operating Module

Part Number	Description
4SZZPL203	FlexAct® UD Central Operation Module Universal working platform equipped with: <ul style="list-style-type: none">– 4-piston diaphragm pump, Sartococon® hydraulic Filter holder, two pressure transmitters and overpressure protection– Peristaltic pump type Watson Marlow 720 UN/R– Control unit with 10,4" touch panel EU 230 V, st. steel version
4SZZPL503	FlexAct® UD Central Operation Module Universal working platform equipped with: <ul style="list-style-type: none">– 4-piston diaphragm pump, Sartococon® hydraulic Filter holder, two pressure transmitters and overpressure protection– Peristaltic pump type Watson Marlow 720 UN/R– Control unit with 10,4" touch panel US 110 V, st. steel version
4SZZPL204	FlexAct® UD Central Operation Module Universal working platform equipped with: <ul style="list-style-type: none">– 4-piston diaphragm pump, Sartococon® hydraulic Filter holder, two pressure transmitters and overpressure protection– Peristaltic pump type Watson Marlow 720 UN/R– Control unit with 10,4" touch panel EU 230 V, powder coated version
4SZZPL504	FlexAct® UD Central Operation Module Universal working platform equipped with: <ul style="list-style-type: none">– 4-piston diaphragm pump, Sartococon® hydraulic Filter holder, two pressure transmitters and overpressure protection– Peristaltic pump type Watson Marlow 720 UN/R– Control unit with 10,4" touch panel US 110 V, powder coated version

2. Consumables

Order number	Description
4UD 1 05 H 27	10 kDa Hydrosart UF
4UD 1 05 H 28	30 kDa Hydrosart UF

Components of bag assembly:

50 L recirculation bag, pressure domes, OPTA® connectors and tubing.

3. Flexel® 3D Palletank®

Palletank® for Magnetic Mixer- without load cells

Order Number Palletank® for Magnetic Mixer w/o load cells

FXC110820	Palletank® 50 L for Impeller Mixing
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Palletank® for Magnetic Mixer- with load cells

Order Number Palletank® for Magnetic Mixer w/o load cells and Combiics 1 Controller

FXC114153	Palletank® 50 L for Impeller Mixing with load cells and CIS1 Combiics controller
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Magnetic Mixer Drive Unit

Part Number Description

LT-DU-005-US	Magnetic Mixer Drive Unit, 110 V, US Power Cord
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LT-DU-006-EU	Magnetic Mixer Drive Unit, 230 V, EU Power Cord
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LT-DU006-UK	Magnetic Mixer Drive Unit, 230 V, UK Power Cord
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LT-DU006-SW	Magnetic Mixer Drive Unit, 230 V, Swiss Power Cord
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LT-DU006-AU	Magnetic Mixer Drive Unit, 230 V, Australian Power Cord
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LT-DU006-JA	Magnetic Mixer Drive Unit, 230 V, Japanese Power Cord and Transformer
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4. Palletank for storage (50-1000 L) | in-process handling (1000 L)

Order Number Palletank

FXC110733	Palletank® 100 L for storage stackable
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FXS102254	Dolly for Palletank® 100 L 200 L (storage & shipping)
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FXC110733	Palletank® 200 L for storage stackable
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FXS102254	Dolly for Palletank® 100 L 200 L (storage & shipping)
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FXC110734	Palletank® 500 L for storage stackable
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FXC100734	Dolly for Palletank® 500 L (storage & shipping)
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FXC106223	Palletank® 1000 L for in-process fluid handling
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FXS102259	Dolly for Palletank® 1000 L for in-Process fluid handling
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4.1 Standard Flexel® 3D bioprocessingbags for Palletank®

Part number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Qty/Box
FXB103341	Flexel® 100 L for Palletank® - Silicone	Silicone	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	5
FXB103364	Flexel® 200 L for Palletank® - Silicone	Silicone	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	5
FXB103376	Flexel® 500 L for Palletank® - Silicone	Silicone	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	1/2" + 11/16" + 0.5 m (20") 1/2" MPX male + sealing cap	5

Part number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Bottom Port 2	Qty/Box
FXB103426	Flexel® 1000 L for Palletank® – Silicone	Silicone	1/2" + 11/16" + 1.5 m (60") 1/2" MPX male + sealing cap	1/2" + 11/16" + 1.5 m (60") 1/2" MPX male + sealing cap	1/2" + 11/16" + 1 m (40") 1/2" MPX male + sealing cap	Plug	5
Part number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110925	Flexel® 100 L for Palletank® – PTE	Silicone + Clear C-Flex® 374	1/2" + 3/4" + 1.5 m (60") 1/2" MPX male + sealing cap	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	1/8" + 1/4" + 1.1 m (40") LL female + needle free sampling port	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	4
FXB110927	Flexel® 200 L for Palletank® – TPE	Silicone + Clear C-Flex® 374	1/2" + 3/4" + 1.5 m (60") 1/2" MPX male + sealing cap	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	1/8" + 1/4" + 1.1 m (40") LL female + needle free sampling port	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB110929	Flexel® 500 L for Palletank® – TPE	Silicone + Clear C-Flex® 374	1/2" + 3/4" + 1.5 m (60") 1/2" MPX male + sealing cap	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	1/8" + 1/4" + 1.1 m (40") LL female + needle free sampling port	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB110930	Flexel® 1000 L for Palletank® – TPE	Silicone + Clear C-Flex® 374	1/2" + 3/4" + 1.5 m (60") 1/2" MPX male + sealing cap	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	1/8" + 1/4" + 1.1 m (40") LL female + needle free sampling port	1/2" + 3/4" + 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111157	Flexel® 1,000 L for Palletank® – HIGH FLOW – TPE	Silicone + Clear C-Flex® 374	1/2" + 3/4" + 1.5 m (60") 1/2" MPX male + sealing cap	3/4" + 1-1/8" + 1.5 m (60") silicone 1-1/2" Tri-Clamp	1/8" + 1/4" + 1.1 m (40") LL female + needle free sampling port	3/4" + 1-1/8" + 1.5 m (60") silicone 1-1/2" Tri-Clamp	2

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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6. Accessories

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

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

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)
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861041	Extraction (including sterilization and or flushing)
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861044	Extraction (non-standard)
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Two pretests may be required for complex products, e.g. formulation buffer and complete solution

861070	Analytical pre-test to identify product interference
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861071	Analytical pre-test with sample preparation
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Number of analyses normally reflects number of extract samples, including blank

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

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany
Phone +49.551.308.0
Fax +49.551.308.3289
www.sartorius-stedim.com/arium-pro

USA Toll-Free +1.800.368.7178
UK +44.1372.737159
France +33.442.845600
Italy +39.055.63.40.41
Spain +34.90.2110935
Japan +81.3.3740.5407

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