

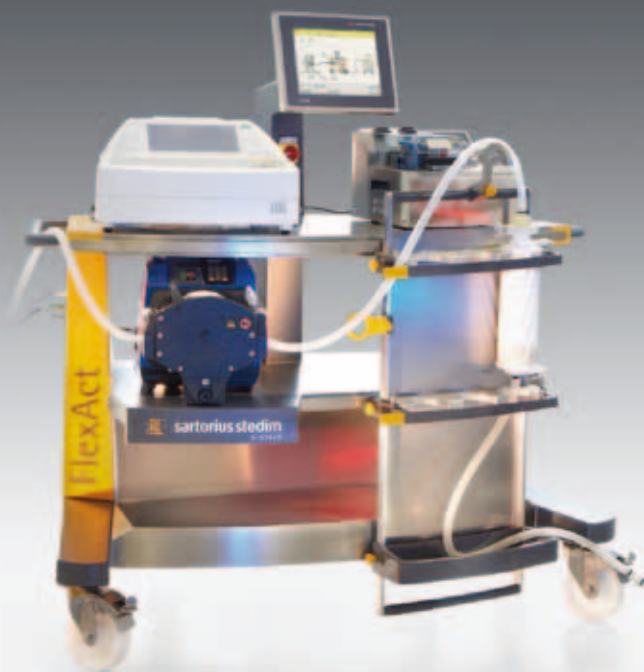


**sartorius stedim**  
biotech

## FlexAct<sup>®</sup> MP

Disposable Solution For Media Preparation

Configurable Disposable Solutions



The FlexAct<sup>®</sup> MP is a standardized configurable disposable solution (CDS) dedicated to media preparation in biopharmaceutical processes.

### Features

- Multifunctional Central Operating Module
- Tailored bag configurations
- 50 – 1,000 L working volumes
- Quick system set-up
- Integrated disposable sensors (p, pH, T)
- Bidirectional operation

### Benefits

- Operator friendly
- Flexible media supply
- Fully scalable
- Efficient equipment utilization
- Enables monitoring
- Highly flexible



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## Description

The FlexAct® MP is a standardized configurable disposable solution (CDS) dedicated to media preparation in biopharmaceutical processes. The FlexAct® MP addresses the entire development cycle and production capacity needs from 50 to 1,000 L for media preparation. The integration of monitoring & control features for pH, temperature, 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 media preparation operation. Combined with a Flexel® for Magnetic Mixer1 and Palletank® the multifunctional Central Operating Module enables the user to install, operate and monitor a fully single use unit operation.

## Components

The FlexAct® MP configurable media preparation solution consists of:

Re-usable equipments :

- Palletank® for Magnetic Mixer with load cells or on Weighing platform,
- Powder Bag Holder,
- FlexAct® COM Central Operating Module with accessories,
- Palletank® for storage.

Single-use pre-configured assemblies :

- Flexel® Bag for Magnetic Mixer,
- Powder Transfer Bags (15 L or 30 L)
- Manifolded or single Flexel® Bag for storage.

### 1. Overview: Flexel® for Magnetic Mixer

Flexel® for Magnetic Mixer is a single-use, high performance mixing solution using Sartorius Stedim Biotech Flexel® 3D Bags, the proven Palletank® technology and ATMI patented Mixing Technology. The system consists of three separate components designed to fit together to offer a maximum process flexibility

**1.1 Palletank® for Magnetic Mixing** – These stainless steel containers are designed to perfectly fit with the Flexel® Bags for Magnetic Mixer integrated with the bottom centered impeller and include a railed port interface for the coupling of the mobile Drive Unit.

**1.2 Magnetic Drive Unit** – Magnetic Mixer Drive Unit generates the rotation of the single-use magnetic impeller coupled to a non-shedding ceramic bearing, enabling Flexel® for Magnetic Mixer to efficiently dissolve and disperse powders, suspensions, solutions or mix emulsions. The Magnetic Mixer Drive Unit is mobile, cart-mounted and designed to interface with Palletank® for Magnetic Mixer of different volumes.

**1.3 Flexel® Bag for Magnetic Mixer for FlexAct® MP operations** are available from stock in configuration of 50 L to 1,000 L 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. FlexAct® COM Central Operating Module with accessories

The FlexAct® COM Central Operating Module is designed for operational excellence in media preparation 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 as pressure, pH and temperature. The integrated controller connected to the single-use pH sensor provides the end-user with a controlled pH adjustment, whereas a second controller connected to the single-use pressure sensor maintains a constant pressure for an optimized filtration. For secure fluid level management a weight signal is provided by either load cells that are integrated into the 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, using a Sartocheck® 4 plus integrity tester, will help to quick connect disconnect and test assemblies.

#### 3.1 Sartocheck® 4 plus

Filter Integrity Testing is an essential procedure to detect defective filter cartridges before or after use. Thus automatic integrity testers have to fulfill highest standards with respect to accuracy and reliability. The Sartocheck® 4 plus is the result of Sartorius'30 years experience in developing automatic filter integrity testers. Valuable productivity enhancing features and robust build quality have been combined with incredible ease of use to make the Sartocheck® 4 plus the only logical choice for integrity testing.

#### 3.2 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 Sartorius Stedim Biotech made BioWelder® and BioSealer® to the product of choice in the biopharmaceutical industry.

4. FlexAct® MP Bag Assemblies with Palletank® for Media Storage

FlexAct® MP bag assemblies are supplied to serve the need of a fully preconfigured, ready to install, single use unit operation. Uniquely, the Flexel® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing Bags are supplied in one package.

The Flexel® Bag assemblies for Magnetic Mixer contains a centred magnetic impeller. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The patented protection cap provides robustness avoiding frictions of the impeller with the film during transport and before bag use. It also offers a large 8" diameter port for powder transfer and allows for continuous mixing during fluid transfer operations and minimizes hold up volume for 100% fluid recovery. The integrated single-use pH and pressure sensors coupled with a thermowell for temperature probe's insertion provide the end-user with a control of the process parameters. The storage bag assemblies of the FlexAct® MP Configurable Disposable Solution are tailored to suit the dedicated need for individual media solution volumes at the point of use, with outlet lines specifically designed for connection either to a stainless steel tank or to a single-use bioreactor from Sartorius Stedim Biotech. The Palletank® for Storage or for In-Process Handling are stainless steel container designed to perfectly fit with the Flexel® 3D Bioprocessing Bag assemblies.

4.1 Powder Transfer Bags

Powder Transfer Bags provide a cost-effective and efficient system for handling pharmaceutical powders in a safe and contained manner. They incorporate antistatic film, ergonomic handles and industry-standard triclamp connectors.

FlexAct® Configurator

A configurator based selection system enables the user to flexibly create the FlexAct® MP solution that meets its process requirements in media preparation. 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 Biotech specialists have analyzed the process environment and the operating procedure for media preparation thoroughly and developed an operator friendly multi-functional Central Operating Unit. Tailored bag configurations with 50 L up to 1,000 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® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing 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® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing 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<sup>-6</sup> over the shelf life.

Flexel® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing Bags are tested for compliance to:

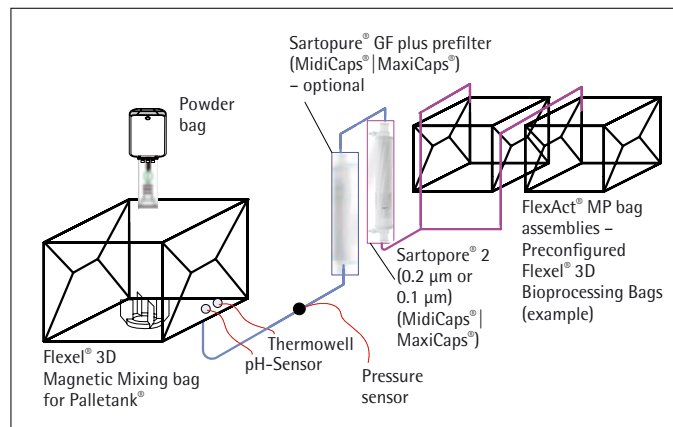
- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19 : Particulate
- ISO 11737 : Bioburden
- ISO 11137 : Sterilization of Medical Devices

### Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations. 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 below shows the bag assemblies connected. As an option a Sartopore® GF plus prefilter is connected with the Sartopore® 2 sterilizing grade filter (also configurable with Sartopore® 2 Mycoplasma retentive filter).

Due to the type of media and feed the filterability may be different. Therefore filterability and scaleup trials are recommended to define the appropriate prefilter in retention rate and size.

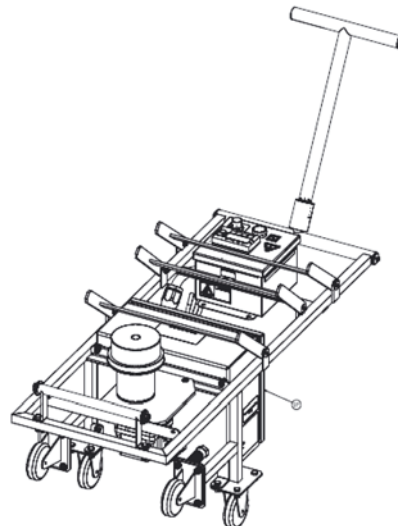


## Specifications

### 1. Magnetic Mixer Drive Unit

The Magnetic Mixer Drive Unit generates the rotation of the single-use magnetic impeller located inside the single use bag assemblies. The Magnetic Mixer Drive Unit is mobile, cart-mounted and designed to interface with Palletank® for Magnetic Mixer of different volumes.

Power:	
– EU	– Single Phase 230 V, 50   60 Hz
– Japan	– Japan Single Phase 230 V, Transformer (110 V Input), 50   60 Hz
– USA	– Single Phase 110 V, 60 Hz
Input Wattage	< 150 Watts
Footprint	84 × 41 cm (33 in × 16 in)
Drive Unit Height	104 cm (41 in), to top of handle
Weight	25 kg (55 lb)
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
Impeller Speed	0 – 300 RPM
Initial Set-up Time	Not applicable
Vessel Changeover	< 7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316L

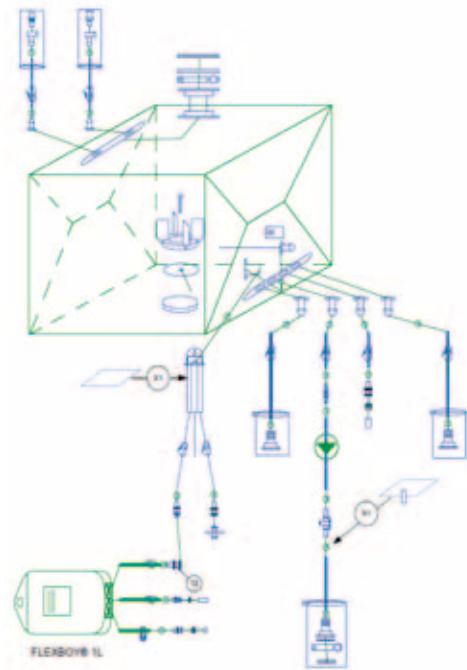




## 2. FlexAct® MP Bag Assemblies

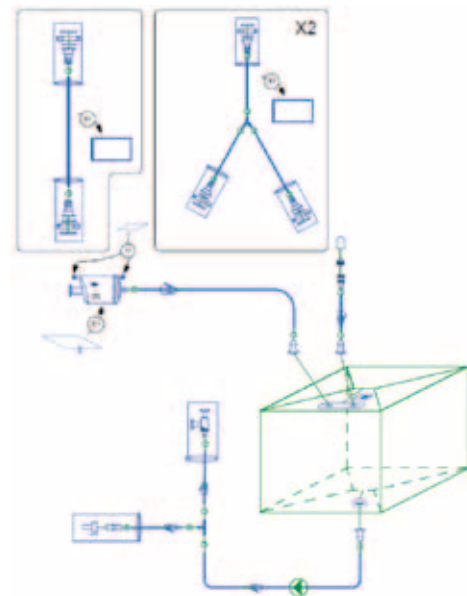
### 2.1. Flexel® Bags for Magnetic Mixer

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, PE Contact Layer
Impeller position	Centered
Impeller size	50 – 1,000 L: 6.35" (161 mm)
Tubing material	Silicone
Number of Ports	4 bottom ports for WFI filling and media emptying, 2 top ports for pH adjustment, 1 top powder port.
pH probe	Single-use glass pH electrode
Thermowell	Silicone thermowell for T probe element (reusable)
Pressure sensor	Single-use pressure sensor on outlet
Fittings	Tri-clamp, Quick Connector, Luer Lock female with needle free sampling port
Volumes	50 L, 100 L, 200 L, 400 L, 650 L and 1,000 L
Sterilization	by Gamma Irradiation



### 2.2. Flexel® 3D Bioprocessing Bag for Storage

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, PE 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, SIP connector, Quick Connector
Volumes	20 L, 50 L, 100 L, 200 L, 500 L, 1,000 L
Sterilization	by Gamma Irradiation
Transfer sets	1.5 bar rated lines for connection of one or two prefilters



## 2.3 Powder Transfer Bags

Bag Chamber	Multiple layer film construction, including Permanently Static Dissipative (PSD) LDPE contact layer
Fittings	4-inch triclamp
Accessory	Pinch clamp
Volumes	15 L and 30 L
Number of Port	1 port
Irradiation	25–45 kGy

Standard Powder Transfer Bag System is designed for powder delivery applications where high containment, high product recovery and ease of use are important. Standard Powder Transfer Bags provide a single-use alternative to traditional rigid reusable containers and plastic pouches in a large variety of powder containment and delivery applications. With a volume range of 15 L and 30 L, the Standard Powder Transfer Bags are routinely used at all process scales from process development to commercial bio-manufacturing. These bags are manufactured with very high quality standards for applications requiring remarkable levels of robustness, reliability and security.

With an extensive range of accessories, Standard Powder Bag Transfer System facilitates the delivery and discharge of powders into Sartorius Stedim Biotech single use mixing systems (Flexel® for LevMixer® and for Magnetic Mixer). The Standard Powder Bag Transfer System is based on the market leading Sartorius Stedim Biotech Flexel® 3D Bag, the proven Palletank® technology and the patent-pending PSD film technology from ATMI.

All powder transfer bags are equipped with Tri-Clamp connectors for powder charging. For media preparation, the contained powder transfer bags can be connected to the mixing bag. After discharge, bags remain connected to the mixing bags in order to minimize the operator exposure.

Standard Powder Transfer Bags provide:

- High product recovery with an ultra clean, antistatic, <USP> Class VI, LDPE film
- High containment to protect the operator, eliminate potential safety risk and avoid the contamination of the work environment during handling, transfer or transport of the fine powder
- Good ergonomics with an extensive range of accessories (complete solution)
- Comprehensive validation package



Powder Transfer Bag and Accessories



## Powder Transfer Bags Holders

Description	Powder holder accessory for 50–100 L Palletank® for Magnetic Mixer	Powder holder accessory for 200–400–650 L Palletank® for Magnetic Mixer	Powder holder accessory for 1,000 L Palletank® for Magnetic Mixer
Construction Material	304 L Stainless Steel and Nylon		
Surface Finishing	Glass Bead Blasted		
Weight (Approx.)	8 kg	9 kg	9 kg
Overall dimensions (Approx.) w × d × h	442 × 400 × 1,080 mm 17.4 × 15.7 × 42.5 in.	743 × 400 × 1,080 mm 29.2 × 15.7 × 42.5 in.	857 × 400 × 1,080 mm 33.7 × 15.7 × 42.5 in.
Height above Palletank® with 15 L Powder Transfer Bag	726 mm   28.6 in.	986 mm   38.8 in.	726 mm   28.6 in.
Height above Palletank® with 30 L Powder Transfer Bag	986 mm   38.8 in.	726 mm   28.6 in.	986 mm   38.8 in.
Additional features	Two vertical positions for 15 L and 30 L Powder Transfer Bags. Rotary powder holder for easy access to the hook		



## Filterability of media and feed

Media and feed have different filterabilities due to various components and concentrations. Therefore filterability and scale-up trials can optimize the economics of the filtration train by selecting appropriate prefilter retention rates and sizes.

Sartorius Stedim Biotech has a large filterability database due to the partnership with SAFC. It is always recommended to perform indication and verification filterability trials to find the optimal filter combination for the media type and volume.

Filterability and scale-up trials with SartoScale filtration units performed by SSB's application specialists simplify the optimization process.

## 2.4 Sartopure® GF plus Prefilters

Sartopure® GF Plus absorptive depth filter are designed for removal of contaminants like colloids, lipids, protein aggregates (Host Cell Protein) and particles from biopharmaceutical fluids. They are used for protection of membrane filters, chromatography columns, ultrafiltration systems in pharmaceutical and biotechnological production processes.

### Cost Saving

The efficient protection of downstream membrane filters and purification equipment saves filter costs and helps to increase the yield of biotech production processes. Moreover, the use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

### Flexibility

Sartopure® GF Plus MaxiCaps® are available with various filtration areas from 0.4 m² | 4 ft² up to 1.6 m² | 18 ft² for easy adoption to any filtration process independent from the batch size.

### Scalability

Consistent and predictable scale-up and down trials can reliably be performed as all Sartopure® GF Plus filter elements are produced with the same type of membrane and identical materials of construction.

### Documentation

Sartopure® GF Plus MaxiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.





## 2.5 Sartopore® 2 Gamma – Midicaps® and MaxiCaps®

Sartopore® 2 Gamma Midicaps® and MaxiCaps® are designed for connection to flexible-bag-container-systems prior to sterilization by gamma-irradiation. They are available with 0.2 µm & 0.1 µm final membranes for sterilizing grade filtration and Mycoplasma removal.

- Applications: Typical applications include sterilizing grade filtration and Mycoplasma removal of: – Biologicals – Pharmaceuticals – Cell Culture Media (serum free or serum containing) – Culture Media Components – Serum – Buffers.
- Compatibility: Sartopore® 2 Gamma Midicaps® and MaxiCaps® are designed for sterilization by gamma irradiation < 50 kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore® 2 Gamma MaxiCaps® offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for filtration of high and low pH-buffers in the Pharma| Biotech field.
- Performance: Due to the superior construction including a "built-in" prefiltration by a heterogeneous double layer membrane Sartopore® 2 Gamma Midicaps® and MaxiCaps® achieve outstanding total throughputs and excellent flow rates.
- Flexibility: Sartopore® 2 Gamma MaxiCaps® are ideally suited to be used in small and large scale filtration applications in combination with flexible bag containers due to their superior effective filtration area of up to 1.8 m²/18 ft² per 30" element.
- Microbiological Retention: Sartopore® 2 Gamma Midicaps® and MaxiCaps® 0.2 µm & 0.1 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines. In addition Sartopore® 2 Gamma Midicaps® and MaxiCaps® are validated for Mycoplasma removal with a LRV of 7 for *Acholeplasma Laidlawii*.
- Quality Control: Each individual element is tested for integrity by B.-P. (0.2 µm only) and Diffusion-Test prior to be released assuring absolute reliability.
- Documentation: Sartopore® 2 Gamma Midicaps® and MaxiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

2.6 Transfer Lines for Acid-Base Titration

Two transfer lines are specifically designed for acid and base titration after connection to the top of the Flexel® Bag for Magnetic Mixer.

Lengths are calculated to allow the mixing bag's emptying without the need for line's disconnection. The contained addition provides the end-user with a safe pH adjustment.

Diameters are chosen for pumping on either a 1/4" ID silicone tubing or 1/8" ID silicone tubing depending on the process requirement and using the Watson Marlow dosing pump WM 520U/R2.

Transfer set (Titration)

Tubing Material	Silicone
Fitting	Quick Connector PSU
Length	4 meters (recommended for connection up to 200 L Flexel® Bag for Magnetic Mixer)
Sterilization	by Gamma irradiation



Transfer set (Titration)

Tubing Material	Silicone
Fitting	Quick Connector PSU
Length	5 meters (recommended for connection from 400 L to 1,000 L Bag for Magnetic Mixer)
Sterilization	by Gamma irradiation





### 3. Palletank®

#### 3.1 For Magnetic Mixer with or without load cells

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Door	Front Hinged Door
Windows	Plexiglass
Ports	Railed port for drive unit Front bottom port for bag line access

Volumes (L)	Palletank® For Magnetic Mixer w/o load cells	Dimensions (W × D × H)	Weight (kg   lb) Palletank
50	Palletank® 50 L for Impeller Mixing	825 × 570 × 1,051 mm (32.5 × 22.4 × 41.4 inch)	43 kg   95 lb
100	Palletank® 100 L for Impeller Mixing	825 × 570 × 1,126 mm (32.5 × 22.4 × 44.3 inch)	49 kg   108 lb
200	Palletank® 200 L for Impeller Mixing	777 × 726 × 1,230 mm (30.6 × 28.6 × 48.4 inch)	63 kg   139 lb
400	Palletank® 400 L for Impeller Mixing	941 × 891 × 1,325 mm (37 × 35.1 × 58.3 inch)	88 kg   196 lb
650	Palletank® 650 L for Impeller Mixing	998 × 1,025 × 1,480 mm (39.3 × 40.4 × 58.3 inch)	103 kg   227 lb
1,000	Palletank® 1,000 L for Impeller Mixing	1,139 × 1,167 × 1,650 mm (44.8 × 45.9 × 65.0 inch)	156 kg   344 lb

Volumes (L)	Palletank® For Magnetic Mixer w/ load cells and CAIS1 Controller	Dimensions (W × D × H)	Weight (kg   lb) Palletank®
50	Palletank® 50 L for Impeller Mixing with load cells and CAIS1 Combics controller	849 × 643 × 987 mm (33 × 25 × 38 in)	55 kg   121 lb
100	Palletank® 100 L for Impeller Mixing with load cells and CAIS1 Combics controller	849 × 643 × 1,093 mm (33 × 25 × 43 in)	58 kg   128 lb
200	Palletank® 200 L for Impeller Mixing with load cells and CAIS1 Combics controller	849 × 643 × 1,190 mm (33 × 25 × 46 in)	80 kg   176 lb
400	Palletank® 400 L for Impeller Mixing with load cells and CAIS1 Combics controller	989 × 767 × 1,340 mm (38 × 30 × 52 in)	96 kg   212 lb
650	Palletank® 650 L for Impeller Mixing with load cells and CAIS1 Combics controller	1,127 × 816 × 1,446 mm (44 × 32 × 56 in)	118 kg   260 lb
1,000	Palletank® 1,000 L for Impeller Mixing with load cells and CAIS1 Combics controller	1,236 × 940 × 1,650 mm (48 × 37 × 64 in)	194 kg   427 lb

### 3.2 Pallettank® for Storage

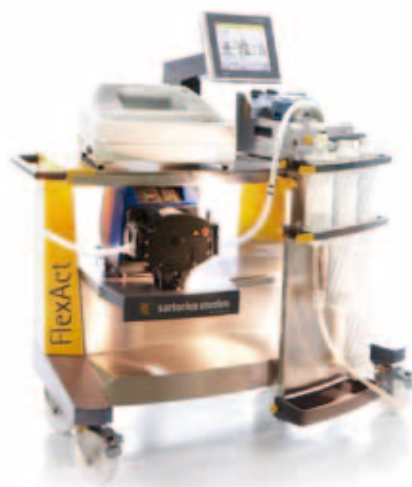
Material	304L Stainless Steel
Surface Finish	Glass Bead Blasted
Stackable	3 (50 – 200 L) 2 (500 L)
Accessory	Dolly

Volume (L)	Dimensions (W × D × H)	Weight (kg   lb) Pallettank®
50	490 × 490 × 750 mm (19,3 × 19,3 × 29,5 in)	24 kg   52,8 lb
100   200	789 × 592 × 891 mm (31,2 × 23,3 × 36 in)	48,4 kg   106,7 lb
500	1192 × 792 × 1010 mm (46,9 × 31,2 × 41,7 in)	88 kg   193 lb
1,000	1260 × 1060 × 1443 mm (49,6 × 41,7 × 59,3 in)	145 kg   318 lb



### 4. FlexAct® MP Central Operating Module

Material	316L Stainless Steel
Surface Finish	Optional: – Powder coated   coloured – Glass Bead Blasted, electropolished
Dimensions	W × D × H 795 × 1,410 × 1,500 mm (31.3 × 55.51 × 59.06 inch)
Weight (approx.)	160 kg (352.74 lb) (incl. Watson Marlow 720 pump)
Control Unit	– Control unit with 10.4" touch panel



#### 4.1 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)





#### 4.2 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



#### 4.3 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)



#### 4.4 Sartocheck® 4 plus

Power requirements	100–240 V AC, 50   60 Hz
Maximum power input	74 watts
Maximum operating pressure	9,999 mbar   145 psi
Minimum inlet pressure	4,000 mbar   58 psi
Dimensions	W × D × H1 × H2 460 × 390 × 140 × 245

#### Measuring Ranges

Test pressure	100–8,000 mbar   1.5–116 psi
Pressure drop	1–2,000 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

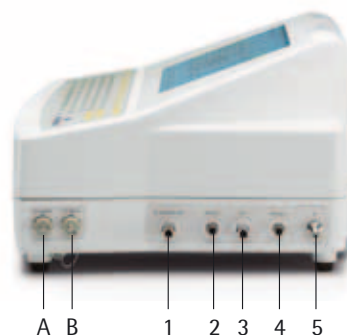
Size	10.4" TFT
Features	256 colors

#### Communication Ports

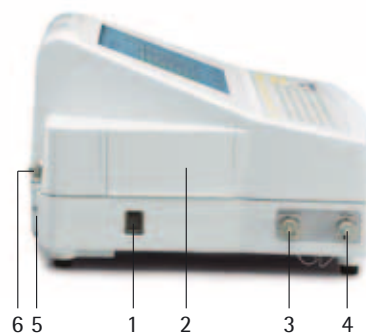
Serial Port	TU RS232
Serial Port	MU RS485
PLC Port	binary signals 12 pins
Network	RJ45

#### Language Option

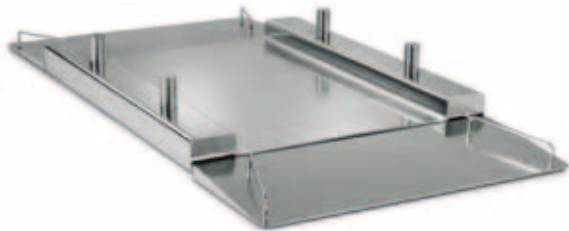
English  
German  
French  
Spanish  
Italian



- 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



## 5. IFS Flat-Bed Scales

### 5.1 IFS4-300LI-I

Weighing capacity	300 kg
Platform size	1,000 × 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	1,250 × 1,250
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)

6. Acid | Base Peristaltic Dosing Pump

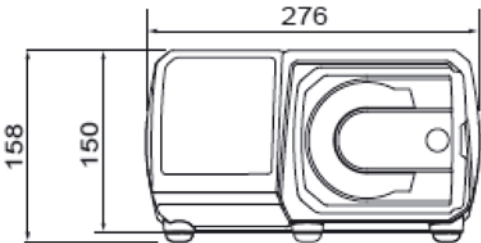
WM 520U|R2

Specification

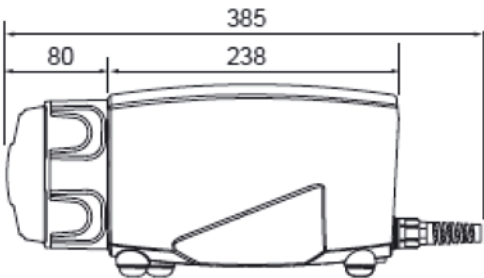
Weight	9.6 kg
Operational Temperature range	5 °C to 40 °C
Noise	< 70 dBb (A) at 1 m
Control Ratio	2200:1
Standards	CE, C ETL US
Supply	110 V   230 V 1 ph, 50   60 Hz

Materials of Construction

Drive casework	Pressure die-cast aluminium LM24
Casework coating	Alocrom pre-treatment exterior grade polyester powder coat
Keypad	Polyester
Switch plate	Glass filled ABS plastic
Rear blanking plate	Stainless Steel 304
Gearbox nose	Aluminium LM24M
Drive shaft	Electroless nickel plated carbon steel



All dimensions in mm



Flow rate ranges (ml/min)		Tube bore and flow rates (ml/min)							
Tube material	Speed	0.5 mm	0.8 mm	1.6 mm	3.2 mm	4.8 mm	6.4 mm	8.0 mm	9.6 mm
Neoprene, Sta-Pure, Chem-Sure, Tygon, Platinum-cured silicone	0.1 to 220 rpm	0.004–9.5	0.01–24	0.04–97	0.18–390	0.40–870	0.70–1,500	1.1–2,400	1.6–3,500
Marprene   Bioprene TL	0.1 to 220 rpm	0.004–9.0	0.01–23	0.04–92	0.17–370	0.38–830	0.67–1,500	1.1–2,300	1.5–3,300

## Ordering information

### 1. Flexel® 3D Palletank®

#### 1.1 Palletank® for Magnetic Mixer – without load cells

Order Number	Palletank® for Magnetic Mixer w/o load cells
FXC110820	Palletank® 50 L for Impeller Mixing
FXC112230	Palletank® 100 L for Impeller Mixing
FXC110821	Palletank® 200 L for Impeller Mixing
FXC111135	Palletank® 400 L for Impeller Mixing
FXC110822	Palletank® 650 L for Impeller Mixing
FXC113384	Palletank® 1,000 L for Impeller Mixing

#### 1.2 Palletank® for Magnetic Mixer – with load cells

Order Number	Palletank® for Magnetic Mixer w/ load cells and Combics 1 Controller
FXC114153	Palletank® 50 L for Impeller Mixing with load cells and CAIS1 Combics controller
FXC114154	Palletank® 100 L for Impeller Mixing with load cells and CAIS1 Combics controller
FXC114155	Palletank® 200 L for Impeller Mixing with load cells and CAIS1 Combics controller
FXC114156	Palletank® 400 L for Impeller Mixing with load cells and CAIS1 Combics controller
FXC114157	Palletank® 650 L for Impeller Mixing with load cells and CAIS1 Combics controller
FXC114158	Palletank® 1,000 L for Impeller Mixing with load cells and CAIS1 Combics controller

#### 1.3 Accessories for Palletank® for Magnetic Mixer

Order Number	
FXA114343	Palletank® Cubical Accessory Powder Bag Holder 50-100 L
FXA114344	Palletank® Cubical Accessory Powder Bag Holder 200-400-650 L
FXA114419	Palletank® Cubical Accessory Powder Bag Holder 1,000 L

#### 1.4 Spare Parts for Palletank® for Magnetic Mixer

Order Number	
FXA112559	Clamp Holder for Palletank® 50 L for Impeller Mixing
FXA112560	Clamp Holder for Palletank® 100 L for Impeller Mixing
FXA112083	Clamp Holder for Palletank® 200 L for Impeller Mixing
FXA112086	Clamp Holder for Palletank® 400 L for Impeller Mixing
FXA112085	Clamp Holder for Palletank® 650 L for Impeller Mixing
FXA113527	Clamp Holder for Palletank® 1,000 L for Impeller Mixing
FXA112074	Adaptation Set for Palletank® for Impeller Mixing

### 1.5 Palletank® for storage (50 – 500 L) | in-process handling (1,000 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® 1,000 L for in-process fluid handling
FXS102259	Dolly for Palletank® 1,000 L for in-Process fluid handling

### 1.6 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)	1,000 × 800	300 kg	10 g	AISI304   1.4301 V2A beadblasted	IP67   IP68
IFS4-1500NN-I floor scale (flat bed scale)	1,250 × 1,250	1,500 kg	50 g	AISI304   1.4301 V2A beadblasted	IP67   IP68

## 1.7 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
SartoConnect PC program set for transferring weights to a PC running Windows® 95/98/NT and for direct further processing using Excel, ACCESS, etc.; incl. connecting cable for CISL and CW1/2/3P	YSC01L
SartoConnect PC program set for transferring weight values to a PC running Windows® 95/98/NT and for direct further processing using Excel, ACCESS, etc.; incl. connecting cable for CISL and CW1/2/3S, connecting cable YCC02-R12F6 or Option M6 required	YSC01I

## 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

## 2. Magnetic Mixer Drive Unit

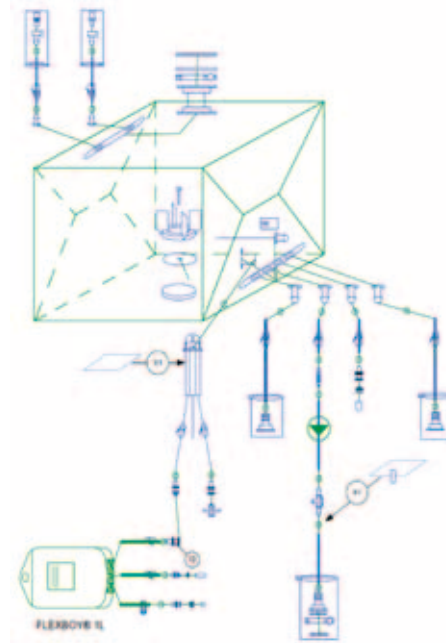
Part Number	Description
LT-DU-005-US	Magnetic Mixer Drive Unit, 110 V, US Power Cord
LT-DU-006-EU	Magnetic Mixer Drive Unit, 230 V, EU Power Cord
LT-DU006-UK	Magnetic Mixer Drive Unit, 230 V, UK Power Cord
LT-DU006-SW	Magnetic Mixer Drive Unit, 230 V, Swiss Power Cord
LT-DU006-AU	Magnetic Mixer Drive Unit, 230 V, Australian Power Cord
LT-DU006-JA	Magnetic Mixer Drive Unit, 230 V, Japanese Power Cord and Transformer

## 3. FlexAct® Central Operating Module

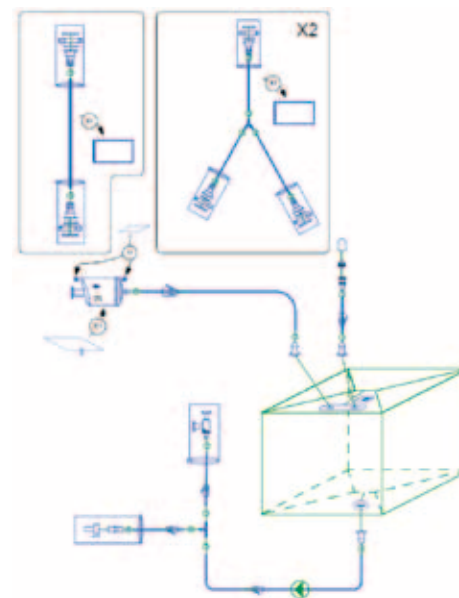
Part Number	Description
4SZZNL201	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10.4" touch panel EU 230 V, st. steel version
4SZZNL501	FlexAct® Central Operation Module Universal working platform equipped 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

#### 4. FlexAct® MP Bag Assemblies

Legend:



Example of Subassembly 1



Example of Subassembly 2

**Bag assemblies with Sartopore® 2 Gamma MidiCaps® and MaxiCaps® 0.45 µm | 0.2 µm**

<b>Part Number</b>	<b>Subassembly 1</b>	<b>Subassembly 2</b>
4MP105E01AC10504	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 50 L (TPE   Sartopore®) Gamma size 9 (0.45   0.2 µm)
4MP105E01AC3AA04	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 3 × 20 L (TPE   Sartopore®) Gamma size 9 (0.45   0.2 µm)
4MP110E01AG11010	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 100 L (TPE   Sartopore®) Gamma – MidiCaps® size 0 (0.45   0.2 µm)
4MP110E01AG2AB10	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 50 L (TPE   Sartopore®) – MidiCaps® size 0 (0.45   0.2 µm)
4MP110E01AG5AC10	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 5 × 20 L (TPE   Sartopore®) – Gamma – MidiCaps® size 0 (0.45   0.2 µm)
4MP120E01AD12005	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 200 L (TPE   Sartopore®) Gamma – MaxiCaps® 10" (0.45   0.2 µm)
4MP120E01AD2AD05	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 100 L (TPE   Sartopore®) – MaxiCaps® 10" (0.45   0.2 µm)
4MP120E01AD3AE05	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 100 L + 2 × 50 L (TPE   Sartopore®) – MaxiCaps® 10" (0.45   0.2 µm)
4MP120E01AD4AF05	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 50 L (TPE   Sartopore®) – MaxiCaps® 10" (0.45   0.2 µm)
4MP140E01AE15006	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 500 L (TPE   Sartopore®) Gamma – MaxiCaps® 20" (0.45   0.2 µm)
4MP140E01AE2AG06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L (TPE   Sartopore®) – MaxiCaps® 20" (0.45   0.2 µm)
4MP140E01AE3AH06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 200 L + 2 × 100 L (TPE   Sartopore®) – MaxiCaps® 20" (0.45   0.2 µm)
4MP140E01AE4AI06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 100 L (TPE   Sartopore®) – MaxiCaps® 20" (0.45   0.2 µm)
4MP140E01AE5AK06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 100 L + 2 × 50 L (TPE   Sartopore®) – MaxiCaps® 20" (0.45   0.2 µm)
4MP165E01AF11T16	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® 1,000 L (TPE   Sartopore®) Gamma – MaxiCaps® 30" (0.45   0.2 µm)
4MP165E01AF3AL16	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 500 L + 1 × 100 L + 1 × 50 L (TPE   Sartopore®) – MaxiCaps® 30" (0.45   0.2 µm)
4MP165E01AF4AM16	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 200 L + 1 × 50 L (TPE   Sartopore®) – MaxiCaps® 30" (0.45   0.2 µm)
4MP165E01AF5AN16	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L + 2 × 100 L + 1 × 50 L (TPE   Sartopore®) – MaxiCaps® 30" (0.45   0.2 µm)
4MP11TE01AF11T16	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 1,000 L (TPE   Sartopore®) Gamma – MaxiCaps® 30" (0.45   0.2 µm)
4MP11TE01AF2AO16	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 500 L (TPE   Sartopore®) – MaxiCaps® 30" (0.45   0.2 µm)
4MP11TE01AF5AP16	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 5 × 200 L (TPE   Sartopore®) – MaxiCaps® 30" (0.45   0.2 µm)

**Bag assemblies with Sartopore® 2 Gamma MidiCaps® and MaxiCaps® 0.2 µm | 0.1 µm**

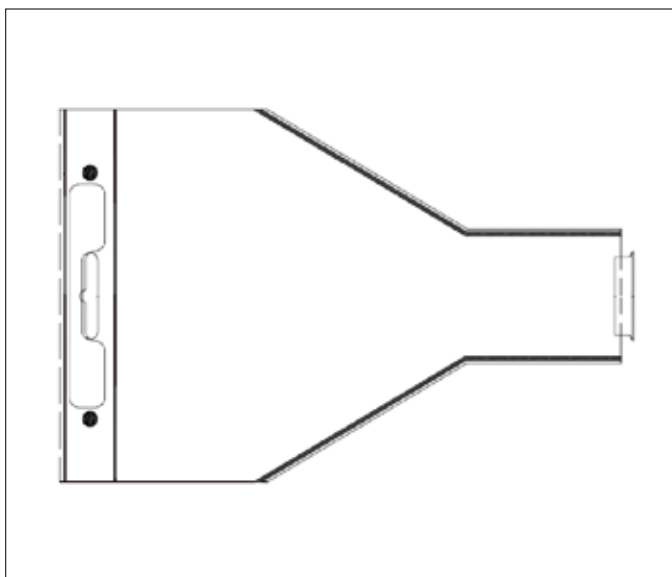
<b>Part Number</b>	<b>Subassembly 1</b>	<b>Subassembly 2</b>
4MP05E01AH10517	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 50 L (TPE   Sartopore®) Gamma size 9 (0.2   0.1 µm)
4MP105E01AH3AA17	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 3 × 20 L (TPE   Sartopore®) Gamma size 9 (0.2   0.1 µm)
4MP110E01AI11018	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 100 L (TPE   Sartopore®) Gamma – MidiCaps® size 0 (0.2   0.1 µm)
4MP110E01AI2AB18	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 50 L (TPE   Sartopore®) – MidiCaps® size 0 (0.2   0.1 µm)
4MP110E01AI5AC18	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 5 × 20 L (TPE   Sartopore®) – Gamma – MidiCaps® size 0 (0.2   0.1 µm)
4MP120E01AJ12019	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 200 L (TPE   Sartopore®) Gamma – MaxiCaps® 10" (0.2   0.1 µm)
4MP120E01AJ2AD19	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 100 L (TPE   Sartopore®) – MaxiCaps® 10" (0.2   0.1 µm)
4MP120E01AJ3AE19	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 100 L + 2 × 50 L (TPE   Sartopore®) – MaxiCaps® 10" (0.2   0.1 µm)
4MP120E01AJ4AF19	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 50 L (TPE   Sartopore®) – MaxiCaps® 10" (0.2   0.1 µm)
4MP140E01AK15020	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 500 L (TPE   Sartopore®) Gamma – MaxiCaps® 20" (0.2   0.1 µm)
4MP140E01AK2AG20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L (TPE   Sartopore®) – MaxiCaps® 20" (0.2   0.1 µm)
4MP140E01AK3AH20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 200 L + 2 × 100 L (TPE   Sartopore®) – MaxiCaps® 20" (0.2   0.1 µm)
4MP140E01AK4AI20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 100 L (TPE   Sartopore®) – MaxiCaps® 20" (0.2   0.1 µm)
4MP140E01AK5AK20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 100 L + 2 × 50 L (TPE   Sartopore®) – MaxiCaps® 20" (0.2   0.1 µm)
4MP165E01AL11T21	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® 1,000 L (TPE   Sartopore®) Gamma – MaxiCaps® 30" (0.2   0.1 µm)
4MP165E01AL3AL21	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 500 L + 1 × 100 L + 1 × 50 L (TPE   Sartopore®) – MaxiCaps® 30" (0.2   0.1 µm)
4MP165E01AL4AM21	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 200 L + 1 × 50 L (TPE   Sartopore®) – MaxiCaps® 30" (0.2   0.1 µm)
4MP165E01AL5AN21	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L + 2 × 100 L + 1 × 50 L (TPE   Sartopore®) – MaxiCaps® 30" (0.2   0.1 µm)
4MP11TE01AL11T21	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 1,000 L (TPE   Sartopore®) Gamma – MaxiCaps® 30" (0.2   0.1 µm)
4MP11TE01AL2AO21	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 500 L (TPE   Sartopore®) – MaxiCaps® 30" (0.2   0.1 µm)
4MP11TE01AL5AP21	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 5 × 200 L (TPE   Sartopore®) – MaxiCaps® 30" (0.2   0.1 µm)



## 4.1 Powder Transfer Bags

### Ordering Information

#### 1. Standard Powder Transfer Bags



Part Number	Description	Bag Port 1	Oty/box
FMA114008	STD Powder Transfer Bag 15 L (PWD Port) with pinch clamp	4-inch triclamp	5
FMA114009	STD Powder Transfer Bag 30 L (PWD Port) with pinch clamp	4-inch triclamp	5

#### 2. Components

Part Number	Description	Oty/box
FMA114007	Component (TC8"-4")	1
FMA114179	Component for TC4" (CAP   Gasket   Union) with pinch clamp	5

#### 3. Powder Bag Holders

Part Number	Description	Oty/box
FXA114343	STD Palletank® Cubical Accessory Powder Holder 50–100 L	1
FXA114344	STD Palletank® Cubical Accessory Powder Holder 200–400–650 L	1
FXA114419	STD Palletank® Cubical Accessory Powder Holder 1,000 L	1

## 5. Accessories

### 5.1 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 ×

## 5.2 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)

### 5.3 BioSealer®

Order Number	Order Code Description
16360-P1	BioSealer®,
16360-P2	Fully automated Tube Sealing Device
16360-P3	Seals tubes with OD 4"-1" and wall thickness 1/16"-3/32"
16360-P4	Optional Parametersets: 1-6**
16360-P5	
16360-P6	
16361-P1	BioSealer®,
16361-P2	Fully automated Tube Sealing Device
16361-P3	Seals tubes with OD 4"-1" and wall thickness 1/16"-3/32"
16361-P4	Equipped with a removable Sealing Head
16361-P5	Optional Parametersets: 1-6**
16361-P6	
16362-P7	BioSealer®,
16362-P8	Fully automated Tube Sealing Device
16362-P9	Seals tubes with OD 5/8"-3/4" and wall thickness 1/8"
16362-P10	Optional Parametersets: 7-12**
16362-P11	
16362-P12	
16363-P7	BioSealer®,
16363-P8	Fully automated Tube Sealing Device
16363-P9	Seals tubes with OD 5/8"-3/4" and wall thickness 1/8"
16363-P10	Equipped with a removable Sealing Head
16363-P11	Optional Parametersets: 7-12**
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

### 5.4 Acid | Base Peristaltic Dosing Pump

#### WM 520U/R2

Order Number	Order Code Description
BB-8840018	WM520U/R2 Peristaltic pump for acid   base dosage

### 5.5 Transfer Lines for Acid-Base Titration

Order Number	Order Code Description
FBT116668	STD Transfer set MPC/MPC (Titration 1) – Length 4 meters
FBT116669	STD Transfer set MPC/MPC (Titration 2) – Length 5 meters

## 6. Validation

### 6.1 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)
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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.

<sup>(1)</sup> This product uses ATMI patented Magnetic Mixer technology

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This product uses ATMI patented Magnet Mixer technology

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

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