

Manual drug product filtration system

STERILE FILTRATION

Standardized hardware and single-use flow kits optimized for PUPSIT

The manual drug product filtration system (Fig 1) has been designed to meet *EU GMP Annex 1: Manufacture of sterile medicinal products*. In addition to the sterile filtration of drug product, it can manually perform pre-use post sterilization integrity testing (PUPSIT) of the sterilizing-grade filters, which is critical to a contamination control strategy. Using decades of experience in PUPSIT design, this ready-to-order PUPSIT solution includes both standardized hardware for consistent installation and standardized consumables for greater flexibility. By reducing the risk of incorrect installation and minimizing the time to implementation, our manual drug product filtration system allows you to meet EU GMP Annex 1 requirements with ease and confidence.

Key features and benefits

- Minimize risk of operator error with easy installation of single-use flow kits
- Reduce time to implementation with ready-to-order standardized hardware and consumables
- Movable valves accommodate a wide variety of single-use flow kits with different filter sizes and configurations

Leak and integrity testing

Integrity and leak testing ensure a defect-free single-use flow kit prior to committing the drug product. The manual drug product filtration system can perform an integrity test, before and after sterile filtration, with the Palltronic Flowstar V integrity test instrument* using bubble point or forward flow (Fig 2). A leak test can be performed with the Palltronic Flowstar LGR integrity test instrument*. Other integrity testers can also be used if desired.

* Palltronic integrity test instruments are provided separately from the system.



Fig 1. Manual drug product filtration system.



Fig 2. Perform leak and integrity testing, before and after sterile filtration.

Minimized risk of incorrect installation

The shadow board graphic guides the operator to correctly install the single-use flow kit to minimize the risk of operator error (Fig 3). The filter holders and valves enable the flow kit to quickly be attached and secured to the shadow board. The flow kit can be installed onto the system in less than 20 min and uninstalled in less than 10 min.



Fig 3. Installation of flow kit with shadow board graphic guide.

Flexibility with movable valves and single-use flow kits

The manual drug product filtration system can fit a wide variety of single-use flow kits. The patented movable valves can be moved along the shadow board graphic (Fig 4) to accommodate flow kits with either small or large filter capsules (Fig 5). This filtration system also fits flow kits with single and redundant filter configurations.

The single-use filtration flow kits are available in a variety of sterilizing-grade membranes including Fluorodyne™ II DFL, Fluorodyne EX EDF, Supor™ EKV, Supor ECV, and Supor Prime membranes. Other membranes can be included upon request. Flow kits are offered with both Kleenpak™ Presto sterile connectors and AseptiQuik connectors. In addition to the single-use filtration flow kits, inlet, flush, and sampling flow kits are also available.



Fig 4. Movable valves can be positioned to fit the flow kit configuration.



Fig 5. Filtration system accommodates flow kits with different filter sizes and configurations.

Pressure monitoring

An integrated pressure transmitter and pressure sensors monitor pressure during sterilizing-grade filtration. Pressure monitoring can be used to detect over pressurization of the single-use flow kit and possible sterility breach (Fig 6). Up to three pressure sensors are included in the flow kit design. When the pressure in the flow kit reaches a specified limit, the pump automatically shuts off, if the pump is plugged into the skid. The e-stop can also deactivate the pump and integrity tester immediately if this equipment is plugged into the skid. An RS232 data logger connection is available to log pressure data from the pressure transmitter (Fig 7).



Fig 6. A Pendotech PMAT pressure transmitter and pressure sensors are integrated into the system. The e-stop will deactivate the pump and integrity tester if this equipment is plugged into the skid.

Minimized footprint

The compact design of the manual drug product filtration system allows it to easily fit into a cleanroom (Fig 8). The footprint is less than 1.1 m² and it can pass through a cleanroom door that is 0.9 m wide or larger. There is sufficient space on the skid to place a Watson Marlow 630 pump and a Palltronic Flowstar V or Palltronic Flowstar LGR filter integrity test instrument. Other pumps and integrity testers can be used if desired.



Fig 8. Compact design allows easy fit into cleanroom.

Services

With over 30 years of experience in single-use design and integrity testing, we support end-users to confidently meet EU GMP Annex 1 requirements. Our service representatives and specialists are available to assist you as you navigate the challenges of implementing PUPSIT.



Fig 7. RS232 data logger connection is available to log pressure data from the pressure transmitter.

Technical specifications

Filtration configurations	Single Redundant (flow kits can have two different membranes if requested)
Minimum filter capsule size	Kleenpak KA02 capsule (200 cm ²) or equivalent
Maximum filter capsule size	Kleenpak Nova NP6 capsule (254 mm [10 in.]) or equivalent
Single-use flow path tube internal diameter (i.d.)	⅜ and ½ in. i.d. ¼ in. i.d. tubing at sampling flow kit
Dimensions (W × H × D)	893 × 1710 × 1100 mm
Weight (without accessories)	145 kg
Materials of construction	
Frame, shadow board, cabinet	Stainless steel 304
External finish	Ra ≤ 0.9 µm
Filter holders, valve plates	Nylon
Bag trays (LGRTPE20L)	High density polyethylene (HDPE) – polyethylene 500 (PE500)
Casters	Polypropylene (PE) and stainless steel
Environmental conditions	5°C to 25°C, relative humidity 10% to 70%, non-condensing
Filtration flow path operational pressure	0 to 3 bar dependent on filters installed Note: Remaining flow path pressure is dependent on chosen flow kits, contact us for detailed information.
Electrical supply	120 to 230 VAC, 50 or 60 Hz, 10 A
System power supply main plug	3-pin industrial plug Power connector plug blue 2P + E, 200 to 250 V/16 A, cable mounting IP44
Valve type	Manual pinch valves
Manual valves specification	IMI Norgren ½ and ⅜ in. i.d. Body: stainless steel 316L
Pressure transmitter specification	Pendotech PMAT3 Range: -0.48 to 5.20 bar Accuracy: ± 2% from 0 to 0.41 bar, ± 3% from 0.41 to 2.07 bar, ± 5% from 2.07 to 4.10 bar
Pump specification	Watson Marlow 630 pump Flow rate with ⅜ in. tubing: 0.18 to 440 L/h Flow rate with ½ in. tubing: 0.24 to 660 L/h

The single-use flow kits meet the following quality standards:

Single-use flow kits

USP <88> Class VI (ISO10993-6, -10, -11)	USP <88> Biological reactivity test <i>In Vivo</i> Class VI ISO10993 Biological evaluation of medical devices part 6, 10 and 11
Animal-derived component-free (ADCF)	A part is first-hand ADCF, or second-hand in compliance with EMA/4/410/01, or EP chapter 5.2.8 monograph 1483
21 CFR Part 177	FDA 21 Code of federal regulations (CFR) Part 177 Indirect food additives: polymers

Validation guide including extractables expectations and particulates claims is available on request.

Our manual drug product filtration system is built according to the following hardware quality standards:

System hardware

EU CE mark	EU declaration of conformity CE-marked-compliant with: • 2014/35/EU Low voltage directive (LVD) • 2014/30/EU EMC directive • 2012/19/EU WEEE (waste electrical and electronic equipment) directive • 2011/65/EU RoHS Directive to the EU/CE section
NRTL (UL/CSA) AS/NZS	Nationally recognized test laboratory for UL (Underwriters Laboratories) compliance for USA and Canada • Electrical safety • FCC 47 CFR Part 15B (ICES-003) • CISPR 11 Group 1 Class A
SJ/T11364-2014	China RoHS-compliance-marked
KS C 9610-6-2: 2019	South Korea EMC-compliance (KC)-marked
KS C 9610-6-4: 2022	

Ordering information

Manual drug product filtration system

Description	Product code
Manual drug product filtration system EU	MANPUPSIT-EU
Manual drug product filtration system UK	MANPUPSIT-UK
Manual drug product filtration system US	MANPUPSIT-US

All system product codes include a shadow board, trolley on casters, pressure transmitter, valves on valve plates, filter holders, sampling bracket, and 1× Allegro tray for biocontainers up to 20 L.

Ancillary equipment

Peristaltic pump Watson Marlow 630 EU	MANPUPSIT-PUMP-EU
Peristaltic pump Watson Marlow 630 UK	MANPUPSIT-PUMP-UK
Peristaltic pump Watson Marlow 630 US	MANPUPSIT-PUMP-US
Palltronic Flowstar V filter integrity test instrument	FFS05
Palltronic Flowstar LGR filter integrity test instrument	FFS04R-LGR
Platform for the Palltronic Flowstar V filter integrity test instrument	MANPUPSIT-PLTFFS05
Platform for the Palltronic Flowstar IV or Palltronic Flowstar LGR filter integrity test instrument	MANPUPSIT-PLTFFS04
Air evacuation mat for a 5 L biocontainer bag	AEDLGR005
Air evacuation mat for a 10 L biocontainer bag	AEDLGR010
Air evacuation mat for a 20 L biocontainer bag	AEDLGR020
Allegro tray for biocontainers up to 20 L	LGRTP20L

Service for manual drug product filtration system hardware

Factory acceptance test (FAT) at Cytiva manufacturing site	MANPUPSITFAT
Installation and operation qualification (IQOQ binder)	29940144
Service to execute IQOQ binder (labor)	28992654
eQualification installation and operation qualification IQOQ	29940148
Service to execute eQualification IQOQ binder (labor)	29940150
Requalification (RQ binder)	29940143
Service to execute RQ binder (labor)	28992654
eQualification requalification RQ	29940149
Service to execute eQualification RQ binder (labor)	29940151
Full care. Our most comprehensive plan. Receive full coverage and one preventive maintenance per year.	Please contact us
Essential care. Proactive preventive maintenance, planned annually. No repair support included.	Please contact us
Extended warranty. Seamless coverage from day one (only available at equipment purchase).	Please contact us
Scientific and laboratory service (SLS) specialist support (per hour)	MSAT06SPH
Scientific and laboratory service (SLS) specialist support (per day)	MSAT06SPD

Single-use flow kits for service

Single PUPSIT single-use system with KA02DFL FAT, non-sterile	X6090-2180NNS
Redundant PUPSIT single-use system with NP6DFL FAT, non-sterile	X6090-2180LNS
Standard PUPSIT inlet single-use flow kit FAT, non-sterile	X6090-2180PNS
Standard PUPSIT inlet single-use flow kit with sampling FAT, non-sterile	X6090-2180QNS
Standard PUPSIT flush bag 20 L FAT, non-sterile	X6090-2182PNS

Contact us to get more information about our service offerings.

Operator training programs

Description	Product code
Manual drug product filtration system operator training program - Licence level 1 (up to five users)	29879667
Manual drug product filtration system operator training program - Licence level 2 (up to 20 users)	29879703
Manual drug product filtration system operator training program - Licence level 3 (unlimited users)	29879666

Manual drug product filtration system single-use flow kits

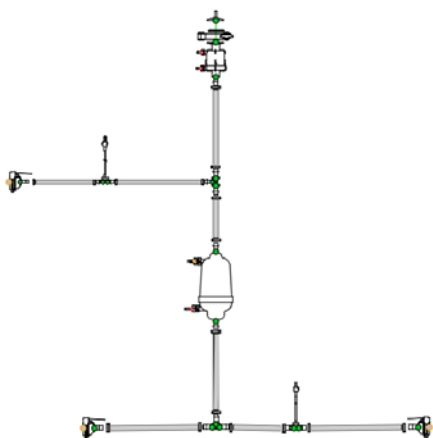


Fig 9. Single filtration single-use flow kit.

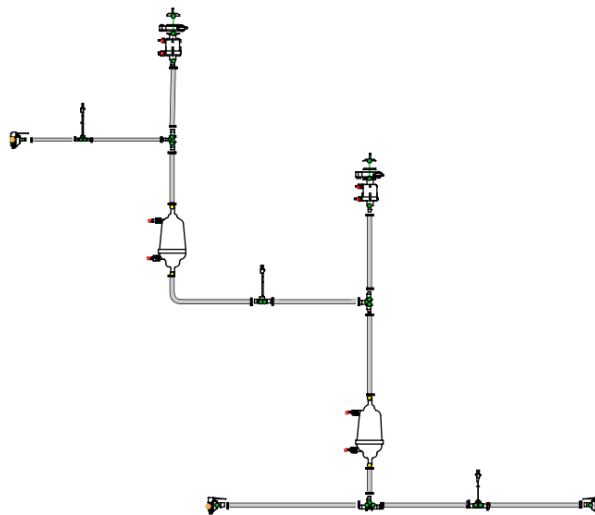


Fig 10. Redundant filtration single-use flow kit.

Single filtration single-use flow kits with Kleenpak Presto sterile connectors (Fig 9)

Minimum order quantity 3 pcs.

Description	Filter membrane	Filter EFA ¹	Product code
Single PUPSIT flow kit with KA02DFL filter and Kleenpak Presto connectors	Fluorodyne II	200 cm ²	6090-2192C
Single PUPSIT flow kit with KA1DFL filter and Kleenpak Presto connectors	Fluorodyne II	400 cm ²	6090-2186U
Single PUPSIT flow kit with KA2DFL filter and Kleenpak Presto connectors	Fluorodyne II	800 cm ²	6090-2186V
Single PUPSIT flow kit with KA3DFL filter and Kleenpak Presto connectors	Fluorodyne II	1500 cm ²	6090-2186W
Single PUPSIT flow kit with NP5LDFL filter and Kleenpak Presto connectors	Fluorodyne II	2700 cm ²	6090-2263J
Single PUPSIT flow kit with NP6DFL filter and Kleenpak Presto connectors	Fluorodyne II	5500 cm ²	6090-2186R
Single PUPSIT flow kit with KA02EKV filter and Kleenpak Presto connector	Supor EKV	220 cm ²	6090-2262X
Single PUPSIT flow kit with KA1EKV filter and Kleenpak Presto connectors	Supor EKV	375 cm ²	6090-2263F
Single PUPSIT flow kit with KA2EKV filter and Kleenpak Presto connectors	Supor EKV	750 cm ²	6090-2263G
Single PUPSIT flow kit with KA3EKV filter and Kleenpak Presto connectors	Supor EKV	1500 cm ²	6090-2263H
Single PUPSIT flow kit with NP5LEKV filter and Kleenpak Presto connectors	Supor EKV	2600 cm ²	6090-2186T
Single PUPSIT flow kit with NP6EKV filter and Kleenpak Presto connectors	Supor EKV	6000 cm ²	6090-2263M
Single PUPSIT flow kit with KA02EDF filter and Kleenpak Presto connectors	Fluorodyne EX	230 cm ²	6090-2262Y
Single PUPSIT flow kit with NP5LUEDF filter and Kleenpak Presto connectors	Fluorodyne EX	5300 cm ²	6090-2263L
Single PUPSIT flow kit with NP6UEDF filter and Kleenpak Presto connectors	Fluorodyne EX	11 000 cm ²	6090-2263T
Single PUPSIT flow kit with KA02ECV filter and Kleenpak Presto connectors	Supor ECV	220 cm ²	6090-2262Z
Single PUPSIT flow kit with NP1LUECV filter and Kleenpak Presto connectors	Supor ECV	1000 cm ²	6090-2267U
Single PUPSIT flow kit with NP5LUECV filter and Kleenpak Presto connectors	Supor ECV	5100 cm ²	6090-2267S
Single PUPSIT flow kit with NP6UECV filter and Kleenpak Presto connectors	Supor ECV	10 400 cm ²	6090-2263U
Single PUPSIT flow kit with FC5UASF filter and Kleenpak Presto connectors	Supor Prime	6100 cm ²	6090-2269B
Single PUPSIT flow kit with FC6UASF filter and Kleenpak Presto connectors	Supor Prime	13 400 cm ²	6090-2269D

¹ Effective filtration area

Single filtration single-use flow kits with AseptiQuik sterile connectors (Fig 9)

Minimum order quantity 3 pcs.

Description	Filter membrane	Filter EFA	Product code
Single PUPSIT flow kit with KA02DFL filter and AseptiQuik connectors	Fluorodyne II	200 cm ²	6090-2274X
Single PUPSIT flow kit with KA1DFL filter and AseptiQuik connectors	Fluorodyne II	400 cm ²	6090-2274Y
Single PUPSIT flow kit with KA2DFL filter and AseptiQuik connectors	Fluorodyne II	800 cm ²	6090-2274Z
Single PUPSIT flow kit with KA3DFL filter and AseptiQuik connectors	Fluorodyne II	1500 cm ²	6090-2275A
Single PUPSIT flow kit with NP5LDFL filter and AseptiQuik connectors	Fluorodyne II	2700 cm ²	6090-2275L
Single PUPSIT flow kit with NP6DFL filter and AseptiQuik connectors	Fluorodyne II	5500 cm ²	6090-2275C
Single PUPSIT flow kit with KA02EKV filter and AseptiQuik connectors	Supor EKV	220 cm ²	6090-2275D
Single PUPSIT flow kit with KA1EKV filter and AseptiQuik connectors	Supor EKV	375 cm ²	6090-2275G
Single PUPSIT flow kit with KA2EKV filter and AseptiQuik connectors	Supor EKV	750 cm ²	6090-2275H
Single PUPSIT flow kit with KA3EKV filter and AseptiQuik connectors	Supor EKV	1500 cm ²	6090-2275J
Single PUPSIT flow kit with NP5LEKV filter and AseptiQuik connectors	Supor EKV	2600 cm ²	6090-2275B
Single PUPSIT flow kit with NP6EKV filter and AseptiQuik connectors	Supor EKV	6000 cm ²	6090-2275P
Single PUPSIT flow kit with KA02EDF filter and AseptiQuik connectors	Fluorodyne EX	230 cm ²	6090-2275E
Single PUPSIT flow kit with NP5LUEDF filter and AseptiQuik connectors	Fluorodyne EX	5300 cm ²	6090-2275M
Single PUPSIT flow kit with NP6UEDF filter and AseptiQuik connectors	Fluorodyne EX	11 000 cm ²	6090-2275Q
Single PUPSIT flow kit with KA02ECV filter and AseptiQuik connectors	Supor ECV	220 cm ²	6090-2275F
Single PUPSIT flow kit with NP1LUECV filter and AseptiQuik connectors	Supor ECV	1000 cm ²	6090-2275K
Single PUPSIT flow kit with NP5LUECV filter and AseptiQuik connectors	Supor ECV	5100 cm ²	6090-2275N
Single PUPSIT flow kit with NP6UECV filter and AseptiQuik connectors	Supor ECV	10 400 cm ²	6090-2275R
Single PUPSIT flow kit with FC5UASF filter and AseptiQuik connectors	Supor Prime	6100 cm ²	6090-2275T
Single PUPSIT flow kit with FC6UASF filter and AseptiQuik connectors	Supor Prime	13 400 cm ²	6090-2275U

Redundant filtration single-use flow kits with Kleenpak Presto sterile connectors (Fig 10)

Minimum order quantity 3 pcs.

Description	Filter membrane	Filter EFA ²	Product code
Redundant PUPSIT flow kit with KA02DFL filters and Kleenpak Presto connectors	Fluorodyne II	200 cm ²	6090-2186P
Redundant PUPSIT flow kit with KA1DFL filters and Kleenpak Presto connectors	Fluorodyne II	400 cm ²	6090-2186J
Redundant PUPSIT flow kit with KA2DFL filters and Kleenpak Presto connectors	Fluorodyne II	800 cm ²	6090-2186H
Redundant PUPSIT flow kit with KA3DFL filters and Kleenpak Presto connectors	Fluorodyne II	1500 cm ²	6090-2186K
Redundant PUPSIT flow kit with NP5LDFL filters and Kleenpak Presto connectors	Fluorodyne II	2700 cm ²	6090-2267R
Redundant PUPSIT flow kit with NP6DFL filters and Kleenpak Presto connectors	Fluorodyne II	5500 cm ²	6090-2192B
Redundant PUPSIT flow kit with KA02EKV filters and Kleenpak Presto connectors	Supor EKV	220 cm ²	6090-2264K
Redundant PUPSIT flow kit with KA1EKV filters and Kleenpak Presto connectors	Supor EKV	375 cm ²	6090-2266C
Redundant PUPSIT flow kit with KA2EKV filters and Kleenpak Presto connectors	Supor EKV	750 cm ²	6090-2266D
Redundant PUPSIT flow kit with KA3EKV filters and Kleenpak Presto connectors	Supor EKV	1500 cm ²	6090-2266E
Redundant PUPSIT flow kit with NP5LEKV filters and Kleenpak Presto connectors	Supor EKV	2600 cm ²	6090-2186G
Redundant PUPSIT flow kit with NP6EKV filters and Kleenpak Presto connectors	Supor EKV	6000 cm ²	6090-2267N
Redundant PUPSIT flow kit with KA02EDF filters and Kleenpak Presto connectors	Fluorodyne EX	230 cm ²	6090-2266A
Redundant PUPSIT flow kit with NP5LUEDF filters and Kleenpak Presto connectors	Fluorodyne EX	5300 cm ²	6090-2266F
Redundant PUPSIT flow kit with NP6UEDF filters and Kleenpak Presto connectors	Fluorodyne EX	11 000 cm ²	6090-2267P
Redundant PUPSIT flow kit with KA02ECV filters and Kleenpak Presto connectors	Supor ECV	220 cm ²	6090-2266B
Redundant PUPSIT flow kit with NP1LUECV filters and Kleenpak Presto connectors	Supor ECV	1000 cm ²	6090-2267V
Redundant PUPSIT flow kit with NP5LUECV filters and Kleenpak Presto connectors	Supor ECV	5100 cm ²	6090-2267T
Redundant PUPSIT flow kit with NP6UECV filters and Kleenpak Presto connectors	Supor ECV	10 400 cm ²	6090-2267Q
Redundant PUPSIT flow kit with FC5UASF filters and Kleenpak Presto connectors	Supor Prime	6100 cm ²	6090-2269C
Redundant PUPSIT flow kit with FC6UASF filters and Kleenpak Presto connectors	Supor Prime	13 400 cm ²	6090-2267X

² EFA is based on a single filter.

Redundant filtration single-use flow kits with AseptiQuik sterile connectors (Fig 10)

Minimum order quantity 3 pcs.

Description	Filter membrane	Filter EFA ³	Product code
Redundant PUPSIT flow kit with KA02DFL filters and AseptiQuik connectors	Fluorodyne II	200 cm ²	6090-2278H
Redundant PUPSIT flow kit with KA1DFL filters and AseptiQuik connectors	Fluorodyne II	400 cm ²	6090-2279Q
Redundant PUPSIT flow kit with KA2DFL filters and AseptiQuik connectors	Fluorodyne II	800 cm ²	6090-2279R
Redundant PUPSIT flow kit with KA3DFL filters and AseptiQuik connectors	Fluorodyne II	1500 cm ²	6090-2279S
Redundant PUPSIT flow kit with NP5LDFL filters and AseptiQuik connectors	Fluorodyne II	2700 cm ²	6090-2280F
Redundant PUPSIT flow kit with NP6DFL filters and AseptiQuik connectors	Fluorodyne II	5500 cm ²	6090-2279X
Redundant PUPSIT flow kit with KA02EKV filters and AseptiQuik connectors	Supor EKV	220 cm ²	6090-2279Y
Redundant PUPSIT flow kit with KA1EKV filters and AseptiQuik connectors	Supor EKV	375 cm ²	6090-2280B
Redundant PUPSIT flow kit with KA2EKV filters and AseptiQuik connectors	Supor EKV	750 cm ²	6090-2280C
Redundant PUPSIT flow kit with KA3EKV filters and AseptiQuik connectors	Supor EKV	1500 cm ²	6090-2280D
Redundant PUPSIT flow kit with NP5LEKV filters and AseptiQuik connectors	Supor EKV	2600 cm ²	6090-2279T
Redundant PUPSIT flow kit with NP6EKV filters and AseptiQuik connectors	Supor EKV	6000 cm ²	6090-2280J
Redundant PUPSIT flow kit with KA02EDF filters and AseptiQuik connectors	Fluorodyne EX	230 cm ²	6090-2279Z
Redundant PUPSIT flow kit with NP5LUEDF filters and AseptiQuik connectors	Fluorodyne EX	5300 cm ²	6090-2280G
Redundant PUPSIT flow kit with NP6UEDF filters and AseptiQuik connectors	Fluorodyne EX	11 000 cm ²	6090-2280K
Redundant PUPSIT flow kit with KA02ECV filters and AseptiQuik connectors	Supor ECV	260 cm ²	6090-2280A
Redundant PUPSIT flow kit with NP1LUECV filters and AseptiQuik connectors	Supor ECV	1000 cm ²	6090-2280E
Redundant PUPSIT flow kit with NP5LUECV filters and AseptiQuik connectors	Supor ECV	5100 cm ²	6090-2280H
Redundant PUPSIT flow kit with NP6UECV filters and AseptiQuik connectors	Supor ECV	10 400 cm ²	6090-2280U
Redundant PUPSIT flow kit with FC5UASF filters and AseptiQuik connectors	Supor Prime	6100 cm ²	6090-2280X
Redundant PUPSIT flow kit with FC6UASF filters and AseptiQuik connectors	Supor Prime	13 400 cm ²	6090-2280Y

³ EFA is based on a single filter.**Ancillary single-use flow kits**

Minimum order quantity 3 pcs.

Description	Product code
Standard PUPSIT inlet single-use flow kit, Kleenpak Presto connectors	6090-2190W
Standard PUPSIT inlet single-use flow kit with sampling, Kleenpak Presto connectors	6090-2192D
Standard PUPSIT flush bag 5 L, Kleenpak Presto connectors	6090-2134S
Standard PUPSIT flush bag 10 L, Kleenpak Presto connectors	6090-2189D
Standard PUPSIT flush bag 20 L, Kleenpak Presto connectors	6090-2190V
Standard PUPSIT flush bag 2 × 20 L, Kleenpak Presto connectors	6090-2189E
Standard PUPSIT inlet single-use flow kit, AseptiQuik connectors	6090-2272Z
Standard PUPSIT inlet single-use flow kit with sampling, AseptiQuik connectors	6090-2273A
Standard PUPSIT flush bag 5 L, AseptiQuik connectors	6090-2273B
Standard PUPSIT flush bag 10 L, AseptiQuik connectors	6090-2273C
Standard PUPSIT flush bag 20 L, AseptiQuik connectors	6090-2273E
Standard PUPSIT flush bag 2 × 20 L, AseptiQuik connectors	6090-2273D



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