

# VALIDATION GUIDE

## FILTRANIOS 31LPS+

Shower Water Filter for 31days Use



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# 1. Introduction

This report contains validation data that demonstrates the suitability of the FILTRANIOS 31LPS+ disposable shower filter to protect against *Legionella pneumophila*.

FILTRANIOS 31LPS+ filter are supplied for installation to a shower hose with a standard 1/2" NPT thread. The product can be used for a maximum of 31days.

The validation guide includes results of testing for the following key features:

- Flow rate testing at various inlet pressures
- Liquid microbial challenge tests using *Legionella pneumophilla* over a 31 day period with simulated flushing cycles.
- Life to blockage tests to indicate expected liquid throughput.
- Chemical compatibility to 1000ppm chlorine and 250ppm peracetic acid.
- Biological reactivity tests to requirements of current ISO10993-1.

## NOTE

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## 2. Quality Assurance

Quality is built into all Parker domnick hunter filtration products through a rigorous product design process, careful selection of suppliers and materials, and manufacture within a highly controlled environment using validated production technologies in adherence to cGMP.

### 2.1. Quality and Environmental Management Systems

Parker domnick hunter is certified by Lloyds Register Quality Assurance to:

- BS EN ISO9001 (current revision): Quality Management Systems
- BS EN ISO14001 (current revision): Environmental Management Standard
- BS EN ISO13485 (current revision): Medical Devices

Copies of the original certificates are available upon request.

### 2.2. Manufacturing Facilities

Parker domnick hunter continues to invest substantially in installation of the latest clean room and manufacturing technology. All manufacturing systems are validated using statistical methodologies (process, product and software) and constantly monitored using statistical process control charts. All personnel within the manufacturing operations are fully trained in cGMP and against competency frameworks to ensure their suitability to operate within specific manufacturing areas.

### 2.3. Material Conformity

Parker domnick hunter works closely with suppliers to ensure materials supplied are of a consistently high quality and also to develop new materials as part of our ongoing product development activity. In addition to supplier certificates of conformity and analysis, incoming raw materials, including moulded parts, membranes and supports, and elastomeric seals, are subject to an appropriate level of incoming inspection. This includes bacterial challenge on each lot of membrane used in the manufacture of sterilising grade filter capsules and cartridges.

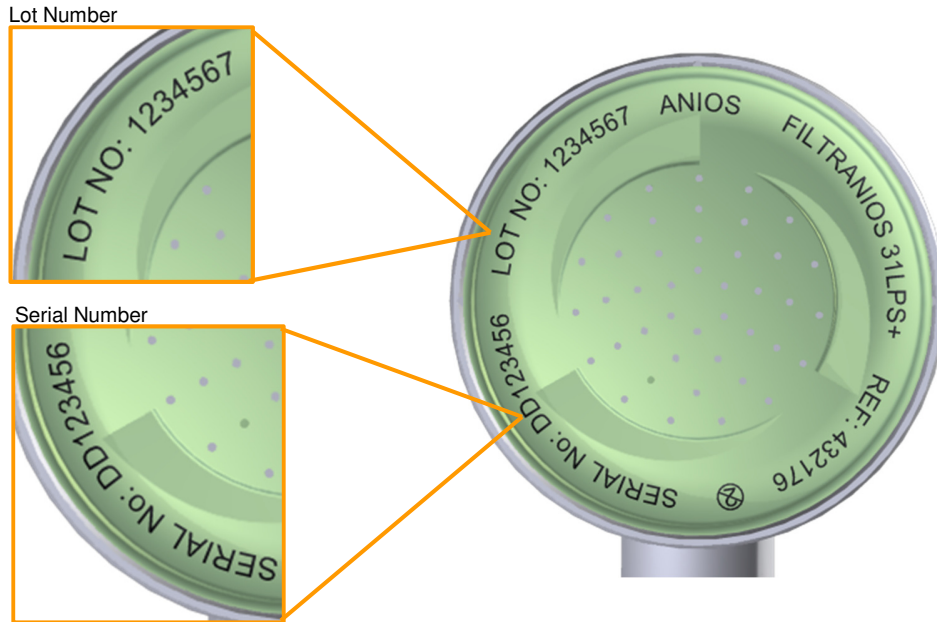
### 2.4. Product and Lot Release Criteria

Prior to shipment all Parker domnick hunter capsules and cartridges undergo final product quality control. 100% of testable products undergo a non-destructive integrity test (diffusional flow). This includes a high volume flush with water that meets or exceeds the current EP and USP standards for purified water. Products are dried using HEPA filtered air and sealed in a protective polyethylene bag within the controlled manufacturing environment prior to final pack and despatch.

In addition a sample is taken from each membrane lot and tested to demonstrate conformity to validated effluent claims and retention to *Brevundimonas diminuta*.

## 2.5. Product Traceability

The product reference and type, lot number and unique serial number are printed on all products. Additionally, the lot number is identified on the protective bag label and the box label within which the product is packed. The serial number provides complete traceability back to pleated materials used in the manufacture of each capsule and the manufacturing processes through the module routing sheet.



The product is also supplied with a unique reference and serial number barcode for the purposes of end-user traceability and product management. The barcode is located on both the product label and the repositionable user record label attached to the protective bag.



Product Label

Repositionable Record Label

## 2.6. Product Shelf Life

The shelf life for FILTRANIOS 31LPS+ products is 3 years.

### 3. Product Description

FILTRANIOS 31LPS+ products have been designed for use in medical POU water filtration applications. All jointed surfaces are assembled by the use of heat sealing technology. No resins or binders are used in the manufacture of the filter and no surfactants are added to aid wetting.

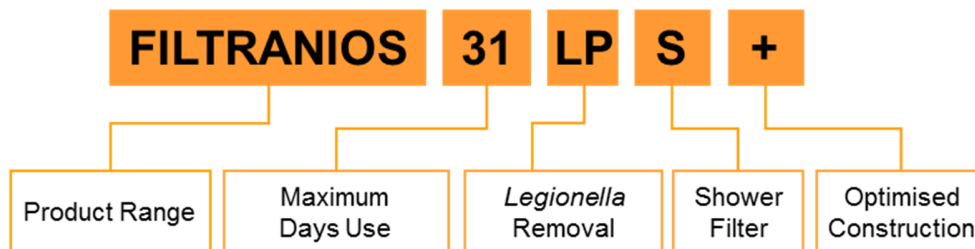
#### 3.1. Materials of construction

All materials used in FILTRANIOS 31LPS+ products meet the requirements of ISO10993-1.

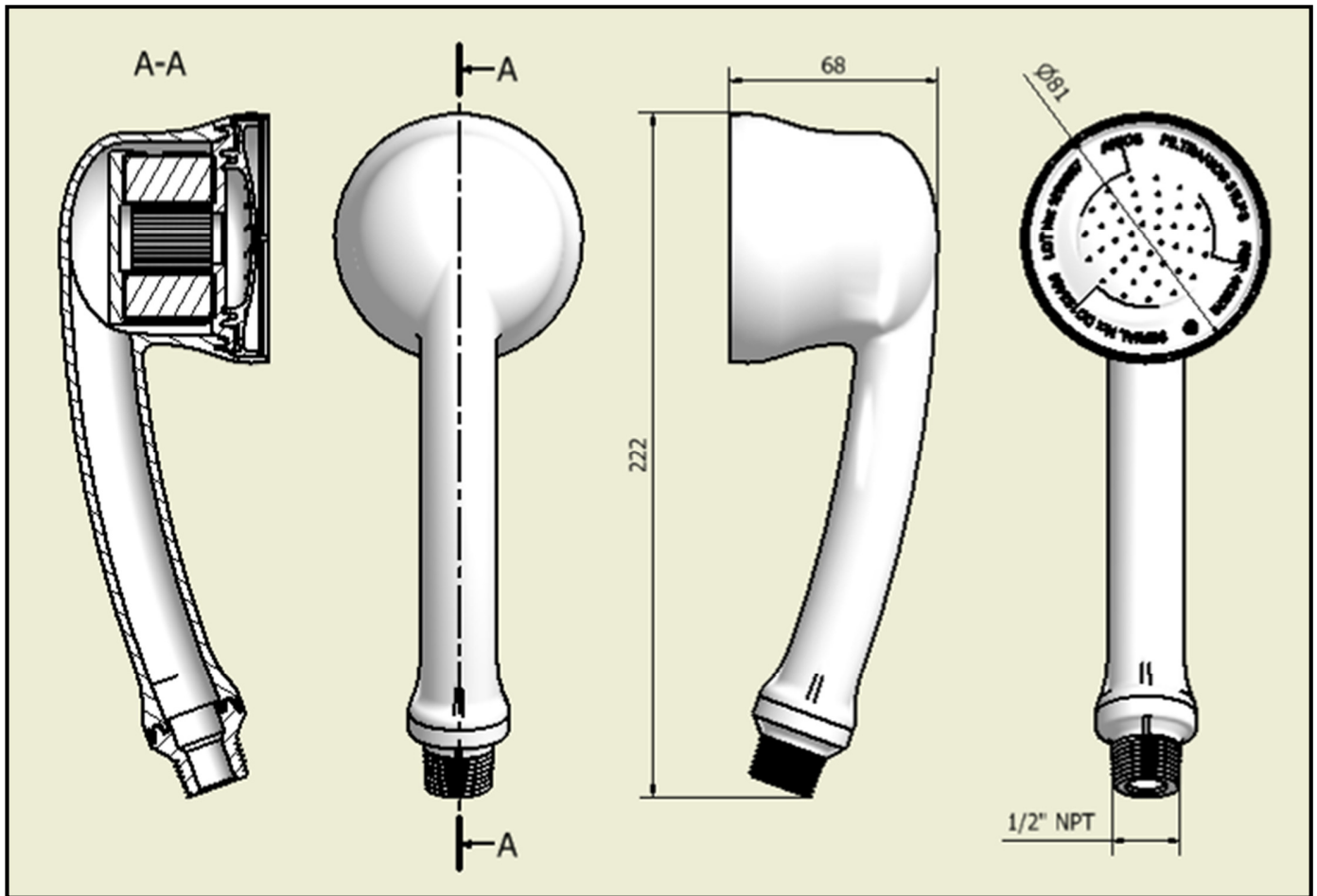
- Filtration Membrane Polyethersulphone
- Pre-filtration Polypropylene
- Upstream Support Polypropylene
- Downstream Support Polypropylene
- Cage Polypropylene
- End-caps Polypropylene
- Capsule body Polypropylene
- Gasket Silicone

#### 3.2. Product Coding

Product code structure indicates the product range, type and maximum use period.



### 3.3. Product Dimensions



## 4. Product Specifications

### 4.1. Capsule Operating Pressure and Temperature

#### Introduction

The purpose of this test was to demonstrate that the FILTRANIOS 31LPS+ shower filters are able to withstand an operating pressure of 5barg at a temperature of 60°C.

#### Summary of methods

Twelve FILTRANIOS 31LPS+ filters from three batches were installed in the test equipment in turn and filled with >60°C water. The filters were allowed to acclimatise until the temperature of the capsule was stable at 60°C. The pressure of the water was increased until the product fractured.

#### Results

Lowest three results shown for each batch.

Batch	Serial No	Temperature (°C)	Burst Pressure (barg)
NOM	DD620877	60.9	11.18
	DD620876	60.1	11.22
	DD620885	60.1	11.50
WCL	DD620896	60.3	11.02
	DD620886	60.3	11.20
	DD620895	60.8	11.32
WCH	DD620873	60.0	11.58
	DD541911	60.5	12.14
	DD541940	60.3	12.20

#### Conclusion

The FILTRANIOS 31LPS+ filters have been shown to be capable of withstanding an operating pressure of 5barg at a temperature of 60°C.



## 4.2. Flow Rates

### Introduction

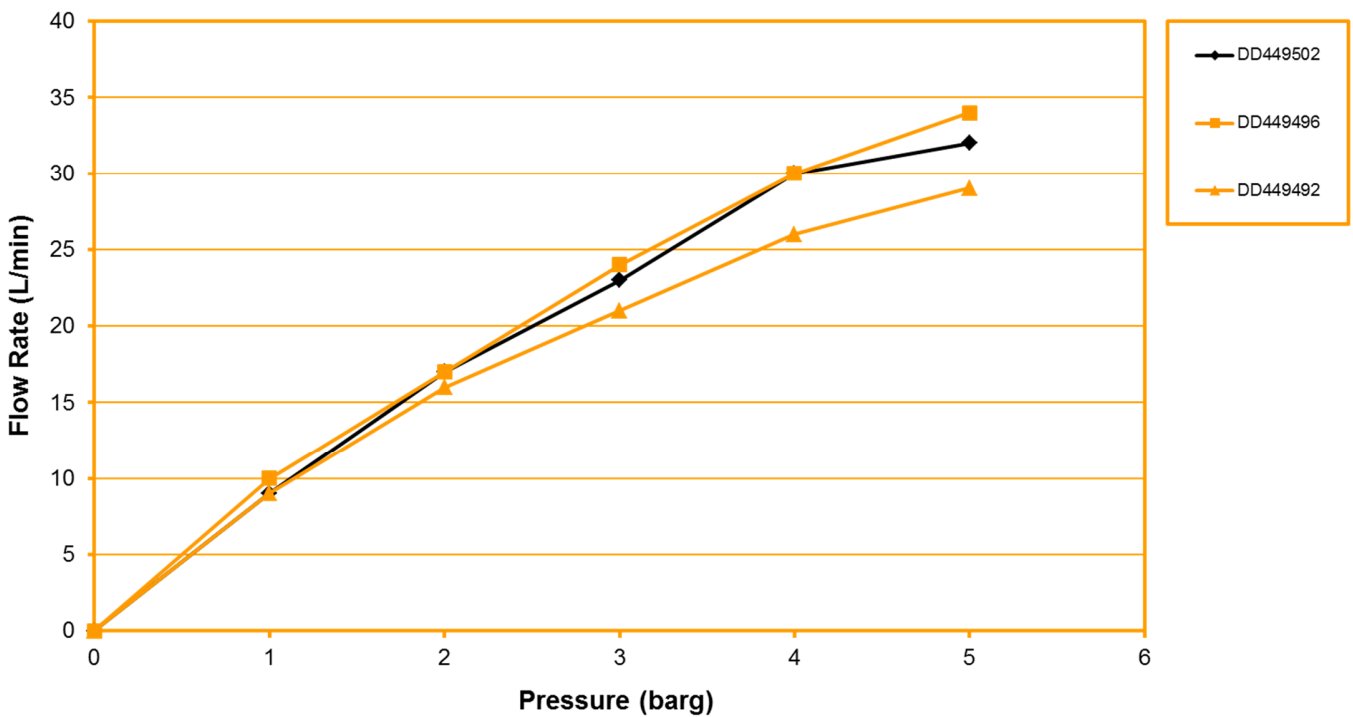
The purpose of this test was to demonstrate the clean water flow rate of FILTRANIOS 31LPS+ filters at various water inlet pressures.

### Summary of methods

FILTRANIOS 31LPS+ filters were installed in the test equipment in turn. The test circuit consisted of a recirculating loop, incorporating a 0.2µm pre-filter. Test filters were fitted to a leg of the test equipment and water diverted through them at pressures ranging from 1 – 5barg in steps of 1barg.

### Results

### Water Flow Characteristics For FILTRANIOS 31LPS+



### Conclusion

FILTRANIOS 31LPS+ filters have typical flow rates of 23 L/min at 3 barg.

### 4.3. Life to blockage

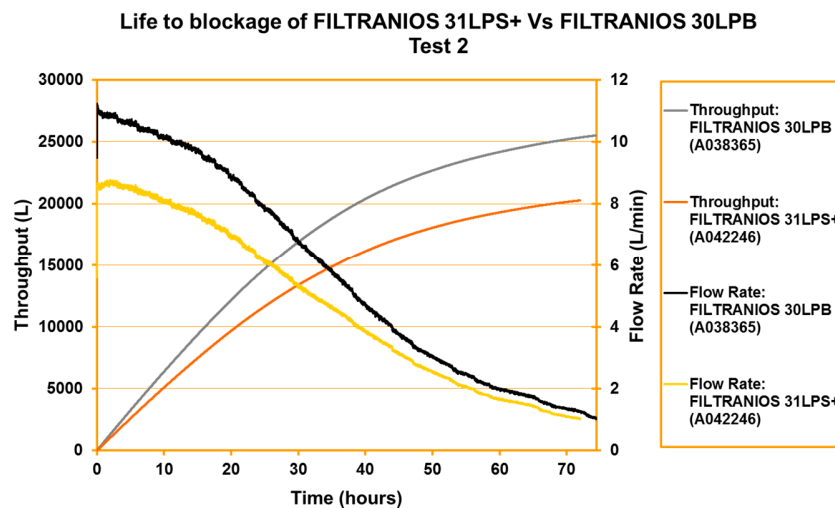
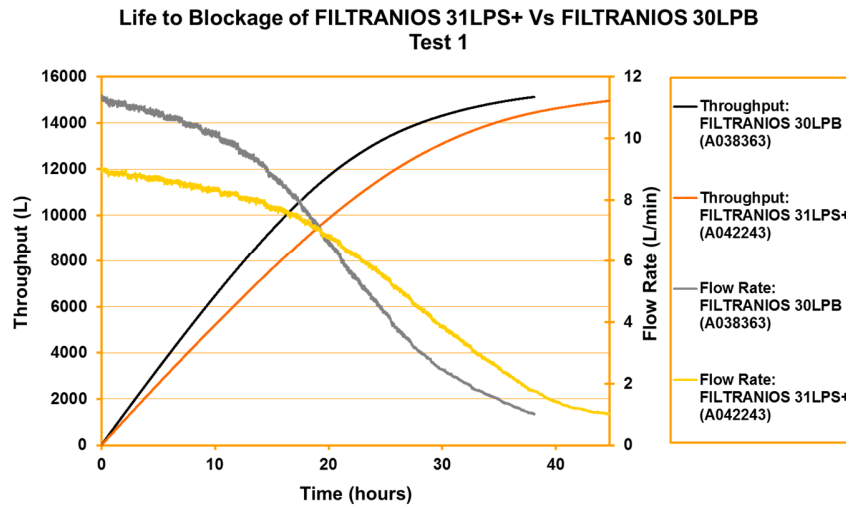
#### Introduction

The purpose of this test was to indicate the typical life to blockage of FILTRANIOS 31LPS+ filters and offer a comparison to a product currently being supplied into the same application.

#### Summary of methods

FILTRANIOS 31LPS+ filters were installed in the test equipment in parallel with a FILTRANIOS 30LPB filter currently being supplied into the same application. The test circuit consisted of a recirculating loop of potable water. In order to maintain a level of contamination, water was constantly drained from the loop and new potable water dosed into it. Test filters were fitted to the test equipment and the water flowed through them at a constant pressure of 2barg. Flow rate and throughput of the each filter was monitored until the flow rate dropped to 1L/min.

#### Results



#### Conclusion

FILTRANIOS 31LPS+ filters were observed to have a similar life to blockage to an existing product currently used in the same application.

Ref: 10143

#### 4.4. Effective Filtration Area (EFA)

Surface Area (cm <sup>2</sup> )	Surface Area (ft <sup>2</sup> )
711	0.77

#### 4.5. Simulated Use *Legionella pneumophila* Retention

##### Introduction

The purpose of this test was to demonstrate that FILTRANIOS 31LPS+ filters are fully retentive to *Legionella pneumophila* throughout their 31 day use.

This test was carried out using a FILTRANIOS 30LPB which utilises the same filtration membrane.

##### Summary of methods

3 FILTRANIOS 30LPB filters from different manufacturing batches were tested by the Health Protection Agency. The micro-filtration industry adopted standard challenge level of  $\geq 10^7$  organisms per square centimeter of effective filtration area was used.

The test equipment consisted of a recirculating loop with sample points upstream and downstream of the test filter. A single bolus of *Legionella pneumophila* serogroup 3 was injected into each filter to achieve a total challenge level of  $\geq 10^7$  organisms/cm<sup>2</sup>. Potable water was pumped through the system at 2.5-3.0L/min for 7 hours per day, Monday to Friday. The test filters were allowed to stagnate for 17 hours per day and at weekends to promote organism growth. Downstream sampling to detect the organism was conducted daily. Testing continued until the test filters had completed 30 flushes and been in contact with the organism for a total of 42days.

##### Results

Serial No	Total flushing time @ 2.5-3.0L/min (hours)	Total Exposure Time (Days)	Downstream Recovery of <i>Legionella pneumophila</i> days 1 - 42 (cfu/mL)
DC004122	210	42	0
DC004126	210	42	0
DC004128	210	42	0

##### Conclusion

FILTRANIOS 30LPB filters were fully retentive to *Legionella pneumophila* sero group 3 when delivered at a minimum bacterial challenge of  $\geq 10^7$  organisms per square centimeter of effective filtration area over an exposure period of 42 days.

The results are valid for FILTRANIOS 31LPS+ filters which utilise the same filtration membrane as FILTRANIOS 31LPB.

## 4.6. Chlorine Compatibility

### Introduction

The purpose of this test was to demonstrate that FILTRANIOS 31LPS+ filters are compatible with 1000ppm chlorine.

### Summary of methods

3 FILTRANIOS 31LPS+ filters were immersed in 1000ppm chlorine and incubated at 40°C for 31days.

The filters were diffusional flow integrity tested pre and post chlorine exposure.

### Results

Serial Number	Pre-exposure Integrity (mL/min)	Integrity post exposure (mL/min)	Pass / Fail
DD662438	1.9	1.5	Pass
DD630083	1.0	1.4	Pass
DD584632	1.2	1.8	Pass

### Conclusion

Following an exposure to 1000ppm chlorine at 40°C for 31days FILTRANIOS 31LPS+ filters remained integral, indicating their compatibility.

## 4.7. Peracetic Acid Compatibility

### Introduction

The purpose of this test was to demonstrate that FILTRANIOS 31LPS+ filters are compatible with 250ppm peracetic acid.

### Summary of methods

3 FILTRANIOS 31LPS+ filters were immersed in 250ppm peracetic acid and incubated at 40 °C for 31 days.

The filters were diffusional flow integrity tested pre and post peracetic acid exposure.

### Results

Serial Number	Pre-exposure Integrity (mL/min)	Integrity post exposure (mL/min)	Pass / Fail
DD576161	0.9	0.9	Pass
DD630085	1.3	1.1	Pass
DD630060	1.4	1.2	Pass

### Conclusion

Following an exposure to 250ppm peracetic acid at 40 °C for 31 days FILTRANIOS 31LPS+ filters remained integral, indicating their compatibility.

## 4.8. Hot Water Sanitisation

### Introduction

The purpose of this test was to demonstrate that the FILTRANIOS 31LPS+ filters were able to withstand a 30minute, 70°C sanitisation cycle at a pressure of 4barg.

### Summary of methods

Nine FILTRANIOS 31LPS+ shower filters, from 3 batches, were each installed in the test equipment and flowed with >70°C. The flow was increased to achieve a 4barg differential pressure. Once the pressure was achieved the filter was flowed for a minimum of 30minutes.

The filters were diffusional flow tested post cycling to indicate integrity.

### Results

Product	Serial Number	Post Test Integrity (mL/min)	Pass / Fail
FILTRANIOS 31LPS+ Shower Filter Batch WCL	DD891788	1.5	Pass
	DD891784	1.5	Pass
	DD891778	1.7	Pass
FILTRANIOS 31LPS+ Shower Filter Batch NOM	DD891790	0.8	Pass
	DD891789	1.5	Pass
	DD891800	1.6	Pass
FILTRANIOS 31LPS+ Shower Filter Batch WCH	DD891803	1.3	Pass
	DD891801	1.0	Pass
	DD891811	1.7	Pass

### Conclusion

The FILTRANIOS 31LPS+ shower filters have been shown to be capable of withstanding a 30minute, 70°C sanitisation cycle at a pressure of 4barg.

## 5. Tests for Biocompatibility

### Introduction

A biocompatibility risk assessment was conducted according to ISO10993-1 for FILTRANIOS 31LPS+ shower filters. The risk assessment concluded that appropriate testing for the devices would be cytotoxicity, irritation and sensitisation.

### Summary of methods

An independent research establishment performed testing to the following standards:

- ISO 10993-5: Part 5 tests for in vitro cytotoxicity
- ISO 10993-10: Part 10 tests for irritation and skin sensitisation

### Results

FILTRANIOS 31LPS+ filters, constructed with the materials listed in the table below passed ISO10993-5 and ISO10993-10 tests.

Component	Material Description
Filtration Membrane	Polyethersulphone
Pre-filtration	Polypropylene
Support layers	Polypropylene
Support cage	Polypropylene
End-caps	Polypropylene, pigment
Capsule body	Polypropylene, pigment
Gasket	Silicone

### Conclusion

FILTRANIOS 31LPS+ shower filters meet the requirements of ISO10993-1.

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