

# PRODUCT SPECIFICATION

<b>Product P/N</b>	<b>2800/10</b>	<b>Mod. 984A Rev. 06</b>
<b>Description</b>	<b>Spiroguard</b>	

## Physical/Mechanical

Approx. Dimensions: **97mm diameter x 79mm height**

Weight: **37g (approx.)**

Interfaces (ex: Input / Output connectors): **OD 34.0mm ID 30.1mm - Machine Side  
OD 30.1mm ID 26.2mm - Patient Side**

Operating temperature Range: **N/A**

Storage temperature Range: **5 °C to 40 °C**

**Bidirectional Filter, Male connector – Patient Side**

## Biological

Pyrogenicity: **<0.3 EU/ml**

**Biocompatibility to ISO10993**

**Category – Surface device**

**Contact – Mucosal Membrane**

**Contact Duration - <24hr**

## Functional

Air Flow Rate: **30l/min, 60l/min, 90l/min.**

Filtration Efficiency: **Filter Efficiency @ 30L/min using TSI 8130: Min. 98.5%**  
(REP: 1245/17 with safety factor applied to Min.)

Pressure Drop:

**Flow Resistance @ 30l/min in accordance with EN ISO 9360-1: Max. 37.4Pa**

**Flow Resistance @ 60l/min in accordance with EN ISO 9360-1: Max. 71.5Pa**

**Flow Resistance @ 90l/min in accordance with EN ISO 9360-1: Max. 119.9Pa**

(REP:1305/17 with 10% of safety margin added to Max.)

Internal Volume: **95ml (approx.)**

Operating Lifetime: **Refer to Instructions for Use.**

Shelf Lifetime: **5 years from the date of manufacture.**

**Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%**  
(*Staphylococcus aureus* @ 30L /minute) REP: EXT607770.

**Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%**  
(*Bacteriophage* @ 30L/ minute) REP: EXT620332.

## Cleanliness

Device assembled within Class 8 Cleanroom.

## Testing

**Torque test @ 10Nm.** (REP: 1344/17)

<b>INSTRUCTIONS / WARNINGS</b>	<i>Multi-language IFU available.</i>
<b>PRODUCT SHELF LIFE</b>	<i>5 years from the date of manufacture. Expiration date and date of manufacture are detailed on the product labelling.</i>