

# MicroGard® II

## Pulmonary function filter Specifications



Regulatory compliance	
EU	Medical Device Class IIa accessory in accordance with Regulation (EU) 2017/745 (MDR)
USA	FDA clearance
China	NMPA clearance
Validated combinations	
Used with:	Jaeger Vyntus™ series Jaeger 3L calibration syringe AioCare with adapter Previous generation: Vmax, MasterScreen, Micro Medical with adapter
Filtration efficiency against cross contamination	
Bacterial and viral (low flow)	99.9999% @ 30 LPM (Liters per minute) <sup>1,2</sup>
Bacterial (high flow)	99.8484% @ 750 LPM (Liters per minute) <sup>3</sup>
Viral (high flow)	99.6851% @ 750 LPM (Liters per minute) <sup>3</sup>
Filter airflow resistance	
Filter only	< 100 Pa*s/L @ 14 L/s (1,02 cmH <sub>2</sub> O*s/L)
Airflow resistance complete breathing circuit	
Filter + Ultrasonic Sensor Vyntus™ USS + FPV	< 150 Pa*s/L @ 14 L/s (1,53 cmH <sub>2</sub> O*s/L) according ATS <sup>4</sup>
Filtering material	
Material	Polypropylene
Method	Electrostatic and mechanical
Filtering layer density (filtering material and three layers scrim)	(258 ± 11%) g/m <sup>2</sup>
Filtering layer diameter (effective)	81 ± 0.5 mm
Filtering layer surface (effective)	(51.5 ± 1.2%) cm <sup>2</sup>
Filter mass: housing and filter material	
MicroGard® IIB	(36 ± 13%) g
MicroGard® IIC	(40 ± 13%) g



MicroGard® IIC round mouthpiece/connector



MicroGard® IIB with integrated oval-shaped mouthpiece

Filter dimensions	
Effective filter volume (excluding adapters and housing)	(55 ± 3%) mL
Connection inner diameter system side	(29.25 ± 2%) mm tapered port
Connection outer diameter patient side (MicroGard® IIC only)	(30.57 ± 2%) mm tapered port
Filter conditions	
Temperature limit use	0-42°C (32-108°F)
Temperature limit storage	0-40°C (32-104°F)
Relative humidity (noncondensing)	10-95%
Materials	
Housing	High Impact Polystyrene (HIPS)
Materials and additives compliant with:	REACH regulations
Filter does not contain:	Bis (2-ethylhexyl) phthalate (DEHP)
	Bisphenol A (BPA)
	Polyvinyl chloride (PVC)
Not made with:	Natural rubber latex
Supplied and used	Non-sterile
Shelf lifetime	3 years
Reprocessing cycle	
Reprocessing cycle for downstreamed parts	6 months <sup>5</sup>

# Mouthpiece

## Specifications

Mouthpiece materials	
Disposable mouthpiece, flex	Polyvinyl chloride (PVC)
Materials and additives compliant with:	REACH regulations
Mouthpiece does not contain:	Bis (2-ethylhexyl) phthalate (DEHP) Bisphenol A (BPA)
Not made with:	Natural rubber latex
Supplied and used	Non-sterile
Mouthpiece conditions	
Temperature limit use	0-42°C (32-108°F)
Temperature limit storage	0-40°C (32-104°F)
Relative humidity (noncondensing)	10-95%
Air pressure use	700-1060 hPa
Air pressure storage	600-1200 hPa



MicroGard® IIC  
with disposable  
mouthpiece, flex

## REFERENCES

- <sup>1</sup> "Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level GLP Report", Nelson Laboratories, UT, Salt Lake City, Study Numbers: 1722703-S01, 1638260-S01, 1487569-S01, 1412078-S01
- <sup>2</sup> "Viral Filtration Efficiency (VFE) at an Increased Challenge Level GLP Report", Nelson Laboratories, UT, Salt Lake City, Study Numbers: 1722702-S01, 1638259-S01, 1487570-S01, 1412080-S01
- <sup>3</sup> UK Health Security Agency, Test Reports: 24-009, 24-024
- <sup>4</sup> ATS Standardization of Spirometry [ATS 2005, p. 332]
- <sup>5</sup> Based on the Bio Burden DIN EN ISO 11737-1: Report 18AA0193

