



**Fraunhofer**

**TESTED<sup>®</sup>  
DEVICE**

B Medical Systems  
PRECISION LINE - F380  
**Report No. BM 2202-1300**

DUPLICATE

Statement of  
Qualification

Single product  
Particle Emission

Customer	B Medical Systems S.à r.l. 17, Op der Hei 9809 Hosingen Luxembourg
Component tested	
Category:	Process Equipment
Subcategory:	Heating and Cooling
Product name:	PRECISION LINE - LABORATORY FREEZER F380 (manufacturing date: 3/7/2022; serial number: 2102290; color: light gray; refrigerant type: R290; weight: 106 kg; volume: 338 l)

Random sampling of particle emissions (airborne) at representative sites

Standards/Guidelines:	ISO 14644-1, -14 The norms stated generally refer to the version valid at the time of the tests.
Test devices:	Optical particle counter: LasAir II 110 and LasAir III 110 with measuring ranges $\geq 0.1 \mu\text{m}$ , $\geq 0.2 \mu\text{m}$ , $\geq 0.3 \mu\text{m}$ , $\geq 0.5 \mu\text{m}$ , $\geq 1.0 \mu\text{m}$ and $\geq 5.0 \mu\text{m}$
Test environment parameters:	<ul style="list-style-type: none"><li>Cleanroom Air Cleanliness Class (according to ISO 14644-1):..... ISO 1</li><li>Airflow velocity:.....0.45 m/s</li><li>Airflow pattern:..... vertical laminar flow</li><li>Temperature: .....22 °C <math>\pm</math> 0.5 °C</li><li>Relative humidity: ..... 45 % <math>\pm</math> 5 %</li></ul>
Test procedure parameters:	<ul style="list-style-type: none"><li>Temperature: ..... T = -32 °C</li></ul>

Test result / Classification	When operated under the specified test conditions, the PRECISION LINE - LABORATORY FREEZER F380 is suitable for use in cleanrooms fulfilling the specifications of the following Air Cleanliness Class according to ISO 14644-1:					
	<table><tr><th>Test parameter(s)</th><th>Air Cleanlines Class</th></tr><tr><td>Temperature = -32 °C</td><td rowspan="2">6</td></tr><tr><td>Overall result</td></tr></table>	Test parameter(s)	Air Cleanlines Class	Temperature = -32 °C	6	Overall result
Test parameter(s)	Air Cleanlines Class					
Temperature = -32 °C	6					
Overall result						
	The material used for the insulating pipe is not suitable for cleanrooms. The material carries a risk of contamination. Therefore, the PRECISION LINE - LABORATORY FREEZER F380 must be used without the insulating pipe.					
	Please note: Transport damages, incorrect installation, oil leakage, aging behavior, corrosion etc. can influence the test result.					

The measuring devices used for the qualification tests are calibrated at regular intervals; their results can be traced back to national and international standards. In cases where no national standards exist, the test procedure implemented complies with the technical regulations and norms applicable at the time of the test. The relevant documentation can be viewed on request at any time.

Detailed information and parameters of the test environment can be found in the Fraunhofer IPA test report.

Fraunhofer Institute for Manufacturing Engineering and Automation IPA	BM 2202-1300 Report No. first document	Stuttgart, June 13, 2022 Place, date of first document issued
Department of Ultraclean Technology and Micromanufacturing	-- Report No. current document	-- Place, current date
Nobelstrasse 12 70569 Stuttgart Germany	on behalf of Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA	