

PARAMETERS AND TESTING METHODS

Test Criteria	Description	Units
Pore size	One dry membrane filter and one wetted with a special liquid are subjected to continuously increasing pressure in a Coulter Porometer; in both cases the air flow through the membrane is measured.	µm
Bubble point DIN 58355 part 2 ASTM F 316	The membrane filter is wetted completely with water or isopropanol (PTFE membranes) and a continuously increasing pressure is applied to the inlet side until air bubbles appear at the outlet side. The bubble point correlates directly with the pore size and can be used to check the integrity of the filter.	bar
Water Flow rate DIN58355 part 1	The time taken for a certain amount of prefiltered deionized water (or ethanol for PTFE filters) to pass through the membrane filter is determined at a vacuum of 0.9 bar.	ml/min/cm ²
Air flow rate	The time taken for the filtration of a defined volume of air (e.g. 100 ml) at a pressure of 3 mbar through a filter area of 6.45 cm ² .	ml/min/cm ²
Thickness	The determination is carried out using callipers with 2 cm ² jaws and a contact pressure of 0.1 bar (100 g/cm ²).	µm
Wetting	A membrane filter with a diameter of 50 mm is placed on water. The time taken for it to become completely wetted is measured.	s
Burst pressure DIN 53 141 part 1	A 10 cm ² membrane sample is stretched over a rubber membrane. A constantly increasing force is applied and the pressure at the moment of bursting is measured.	bar
Extractable components (loss in weight) DIN 58 355 part 6	A membrane filter is weighed, placed in boiling water for 30 minutes, dried and then reweighed. The loss in weight is a measure of the extractable component fraction.	%
Bacterial challenge test DIN 58 355 part 3 ASTM D 3863	A medium containing test bacteria is filtered through the membrane filter (microorganism density 10 ⁷ microorganism/cm ³). After an incubation period of 72 hours the filtrate must show no signs of bacterial growth. Test bacteria: 0.15 µm - <i>Burkholderia cepacia</i> 0.20 µm - <i>Brevundimonas diminuta</i> 0.45 µm - <i>Serratia marcescens</i>	Visual assessment
Checking the sterilization method with bioindicators DIN 58 948 part 8	During the sterilization process test strips with living bacterial spores are applied to the individually packed membranes. These are then incubated in a nutrient solution. After 7 days no turbidity (= bacterial growth) should be visible. Test spores: Ethylene oxide treatment - <i>Bacillus subtilis</i> Gamma radiation - <i>Bacillus pumilus</i>	Visual assessment