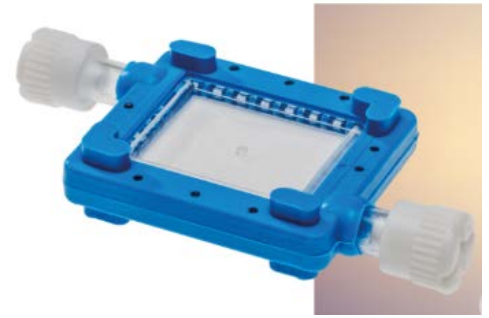


VITVO TECH PIECE

<p>Raw material</p>	<p>TPX (Polymethyl-pentene) oxygenation membranes</p> <p>TPE (Styrene-Ethylene-Butylene-Styrene) frame</p> <p>PET/PBT (Polyester non-woven fabric) three-dimensional matrix</p> <p>Traceability in DMR for each lot</p> <p>Fulfils the criteria of USP grade IV</p> <p>Free of leachable chemical toxic compound according to ISO 10993-18:09</p>
<p>Biological safety</p>	<p>Non-cytotoxic based on ISO 10993-5</p> <p>Free from detectable DNA/RNA</p> <p>Free from detectable DNase/RNase</p> <p>Non-pyrogenic LAL level < 0.06 EU/ml based on EU Ph. 2.6.14</p> <p>Sterility based on EU Ph. 2.6.1</p> <p>Bioburden test based on ISO 11737-1</p>
<p>Functional Attributes</p>	<p>Integrity/Leak test exceed 300mmHg at 25°C</p> <p>Gas exchange rate according to ASTM D3985-05(10)e1 O₂ > 5.000 cc/m²*24h*bar ASTM F 2476-13 CO₂ > 21.000 cc/m²*24h*bar</p> <p>Disposal of the vapor/air according to ASTM E96/E96M-16 ≤ 3,8 g/m²*24h</p> <p>Static priming volume: the max volume capacity 1.1±0.05ml</p> <p>Escape <1 % with the following cell line: A673, TC71, BxPC3, MIA-PACA, SKNBE, SY5Y, Bt549, A172, U87MG, BM-MSC, AT-MSC</p> <p>25 cm² useful Surface, up to 0,4 cm³ equivalent cell mass</p> <p>Operating Temperature: +20° ÷ +38°C</p>



VITVO TECH PIECE

	<p>Operating Humidity: > 95%</p> <p>Operating Atmospheric Pressure: 700 to 1060 mBar (5% CO₂, 0-21% O₂)</p> <p>Operating environmental temperature: from +15° ÷+40°C</p>
Sterlization	<p>Product intended for single use only</p> <p>Beta Ray irradiation, validation method based on ISO 11137-1/3:15 in progress</p>
Storage and Warehousing	<p>Two years shelf life</p> <p>Product packaging QC passing</p> <p>Storage temperature: Temperature: 5° to 35°C</p> <p>Relative humidity: 10-95%</p> <p>Keep away from heat (do not expose to direct sunlight)</p> <p>Keep dry</p>
Quality Management System	<p>Clean room assembly <ISO 8 according ISO14644-1</p> <p>Production cGMP oriented</p> <p>ISO9001:2015 certification (TUV SUD)</p>