



VITVO TECH PIECE

Data traceability	Ref: lot: Description: VITVO Exp. Date:
Raw materials	TPX (Polymethyl-pentene) oxygenation membranes TPE (Styrene-Ethylene-Butylene-Styrene) frame PET/PBT (Polyester non-woven fabric) three-dimensional matrix Traceability in DMR for each lot Fulfils the criteria of USP grade IV Free of leachable chemical toxic compound according to ISO 10993-18:09
Quality Management System	ISO 8 Clean room assembly according to ISO14644-1 cGMP oriented production ISO9001:2015 certification (TUV SUD)
Biological safety tests	Non-cytotoxic based on ISO 10993-5 Free from detectable DNA/RNA Free from detectable DNase/RNase Non-pyrogenic (LAL test) based on EU Ph. 2.6.14 Sterile based on EU Ph. 2.6.1 Bioburden test based on ISO 11737-1
Functional Attributes	Integrity/Leak test exceed 300mmHg at 25°C Gas exchange rate according to: ASTM D3985-05(10)e1 O ₂ > 5.000 cc/m ² *24h*bar ASTM F 2476-13 CO ₂ > 21.000 cc/m ² *24h*bar Disposal of the vapor/air according to: ASTM E96/E96M-16 ≤ 3,8 g/m ² *24h Static priming volume: max volume capacity 1.4±0.2ml Excape <1 % with the following cells: <ul style="list-style-type: none"> - A673, TC71, BxPC3, MIA-PACA, Bt549, Sy5y, SkBr3, A172, U87MG - Primary Lung Adenocarcinoma and Glioblastoma tumors - BM&AT-MSK 25 cm ² useful Surface, up to 0,4 cm ³ equivalent cell mass Operating Temperature: +20° ÷ +38°C Operating Humidity: > 95% Operating Atmospheric Pressure: 700 to 1060 mBar (5% CO ₂ , 0-21% O ₂) Operating environmental temperature: from +15° ÷ +40°C
Sterilization	Product intended for single use only Beta Ray irradiation, validation method based on ISO 11137-1/3:15



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Storage and Warehousing	
	Two years shelf life Product packaging QC passing Storage temperature: Temperature: 5° to 35°C Relative humidity: 10-95% Keep away from heat (do not expose to direct sunlight) Keep dry