

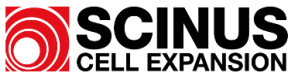


DATASHEET

Osilaris

Designed for cost-efficient manufacturing of cell therapies, from research to decentralized, GMP-compliant clinical settings.

Category	Parameters
Working volume range	~0.05 – 1.2 Liters (up to 1.4L with manual adjustment), expandable with +2 liters in perfusion
Culture bag consumable	<p>Single use, sterile USP Class VI plastic with integrated:</p> <ul style="list-style-type: none"> • In-line optical pH sensor • In-line optical DO sensor • In-line pressure sensor • Weldable Tygon tubing for sterile sampling • Luer lock ports for volume • Cell and microcarrier-retaining filters
Device management	<ul style="list-style-type: none"> • Touchscreen interface with user access control • Remote, LAN control • At-line cell and medium sampling
Carboxygenator	<ul style="list-style-type: none"> • Automated dissolved oxygen (DO) control with O₂ and N₂ • Automated pH control with CO₂
DO range	0 – 500% air saturation with accuracy ± 0.4 % O ₂ at 20.9 % O ₂ , ± 0.05 % O ₂ at 0.2 % O ₂
pH range	5.5 – 8.5 with accuracy ± 0.1 pH (±0.05 pH with single-point calibration in process medium)
Temperature range	Ambient to 45 °C ± 0.01 % accuracy
Rocking	<ul style="list-style-type: none"> • Mechanic rocker-based inversion and mixing by gravity • Tilting angle: 0 - 100° per side • Speed: 0 - 500°/s, one tilt from -100° to +100°/ 400 ms
Data integrity and compliance	<ul style="list-style-type: none"> • On-device data logging, storage & audit trail • 21 CFR Part 11 compliant • EU Annex 1, 11, 15 support with DQ/IQ/OQ • OPC-UA compatible • CE marked • Manufactured under ISO 9001
Physical footprint	86 × 54 × 84 cm, 125 kg



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