

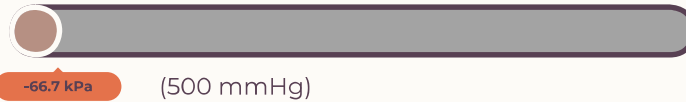
ISO 8637-1:2024 Versus ISO 8637-1:2017

ISO 8637-1:2024 remains largely aligned with ISO 8637-1:2017, with many clauses unchanged or only editorially clarified, so most existing designs and core performance characteristics remain acceptable in principle. The main gaps arise from tighter mechanical/connector requirements and stronger traceability between labeling, test evidence, and risk management.

- External casing negative-pressure endurance is tightened, the device must now withstand negative pressure up to 66.7 kPa (500 mmHg) below atmospheric, instead of the earlier 93.3 kPa (700 mmHg), while still meeting 1.5× the maximum stated positive pressure.

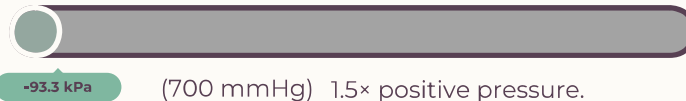
External Casing Negative-Pressure Endurance

New Negative-Pressure Endurance



(500 mmHg)

Old Negative-Pressure Endurance



(700 mmHg) 1.5× positive pressure.