

Tray Sealing Equipment



MD-2420 shuttle tray sealer



MD-1612 table top shuttle tray sealer

SencorpWhite's line of medical tray sealers is 100% validatable and calibratable. The MD Series sealers include standard features such as PLC control system with touch-screen HMI; short cycle indicator; high/low temperature alarm; high/low pressure alarm; resettable cycle counter; external output ports (temperature, pressure and dwell time) for process control verification and calibration; and key switch lockout features to limit access to the set up screens. The units are ISO 11607 compliant and CE compliant. Sample IQ/OQ protocol documents are available with standard models.

By far, validation and meeting FDA regulations cause the biggest concerns for medical device manufacturers. Determining an appropriate sample size for medical device package testing is crucial in the validation of a sterile barrier system. ISO 11607:2006, Part 1 and Technical Information Report TIR 22:2007 are the relevant compliance and guidance documents. TIR 22 provides the detailed procedures necessary for installation qualification (IQ) and operational qualification (OQ).

SPECIFICATIONS

MD-1612

Seal Area: 16" x 12"
 Tray Depth: Up to 3"
 Unit Size (LxWxH): 50" x 39" x 28"
 Seal Force: 5,000 lb
 Press Design: 8" diameter dual cylinder system



Trays

By providing IQ/OQ protocol documents, SencorpWhite helps medical device manufacturers, contract manufacturers, and packagers to set-up testing protocols and document test results. All SencorpWhite MD-Series tray sealers include a full 2-year warranty.

In addition to the MD-1612 table top shuttle tray sealer and MD-2420 shuttle tray sealer, SencorpWhite also offers in-line tray sealing systems.

Tray Sealing Equipment Options:

- Discrete controls interface with hinged, lockable instrument panel cover
- Recipe storage eliminates re-entering your seal parameters and alarms every time you change tooling
- Tool recognition ensures the correct recipe is running with the corresponding tool
- Data acquisition system captures process parameters, alarms, machine status, and more
- PLC program storage device provides backup against lost programs or recipes
- Automated shuttle movement provides ergonomic advantages and more

MD-2420

Seal Area: 24" x 20"
 Tray Depth: Up to 6"
 Unit Size (LxWxH): 75" x 48" x 52"
 Seal Force: 12,000 lb
 Press Design: Toggle press with bump



Tooling

Pouch Sealing Equipment



SencorpWhite's medical pouch sealing systems include constant heat sealers, impulse sealers, and vacuum chamber hot bar pouch sealers.



Pouches

SencorpWhite's medical pouch sealers are 100% validatable and calibratable. All sealers are available in 12" and 24" models with variable seal widths. Table top versions are built on open back frames

allowing front-to-back and lateral pass-thru sealing. All pouch sealers have digital indicators for temperature, pressure, and dwell time. Most models include process alarms with lockout features for all seal parameters and external output ports for process control verification and calibration. P-Series models have optional evacuation/gas flush capabilities.

All units are ISO 11607 and CE compliant and most models come with sample IQ/OQ protocol documents.

Pouch Sealers	AS/1	AS/2	IH/2	P/2	DDS/2	MPK/2
Continuous Heat	√	√		√	√	√
Impulse Heat			√			
Evac/Flush Capable				optional	√	
Process Alarms With Lockouts		√	√	√	√	√
Output Ports		√	√	√	√	√
Seal/Cut						√