DPTE® Transfer Leak Tester (TLT)

Patient safety rhymes with process integrity

GETINGE

DPTE® Transfer Leak Tester (TLT)

Wireless and pipeless integrity tester for DPTE® Alpha and Beta containers

Meet current and future regulations

Patient safety is ensured with an unbroken chain of sterility throughout the process. Quality of production batches must be secured during every step. We know you are under pressure from ever-increasing demands on testing for process integrity. Not least from the new Annex 1 Consultation document of the GMP.
This is why the modernized, wireless Getinge TLT is designed to meet these demands and secure the ease and convenience of checking the integrity of both DPTE® Alpha and rigid Beta parts using pressure with reliable and accurate repeatability.

Getinge's DPTE® Transfer Leak Tester (TLT)

During contained transfer of materials into or out of isolators or other classified environments, or during aseptic container storage between processes, the new operator-friendly TLT allows you to check the integrity of the DPTE® systems prior to or after the production cycles.

- Safe production and process control with a reliable, repeatable, traceable leak detection systems
- Simple and easy to install on both DPTE® Alpha and Beta container, whatever the orientation of the DPTE® assembly tested
- Wireless, paperless and pipeless (no cables and pipes between the remote head and the main unit)
- Full traceability compliant with FDA 21 CFR part 11 and EU Annex 11
- Modern tool supporting the equipment integrity and preventive contamination control strategy as recommended by the international guidelines*
- Compatible with all DPTE® Alpha and rigid Beta parts on the market (105 - 350 mm)
- Based on pressure decay method according to ISO Guidelines
- Full connectivity and traceability with the HMI available either with an external tablet or with onboard version, integrated (through SCADA) for Getinge isolators
- Trolley available with 4 charging stations

* European Commission, EudraLex, Volume 4, EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 1, Manufacture of Sterile Medicinal Products, December 2017 (draft for comment).
FDA Aseptic Processing Guidance
PIC/S Pharma Inspection Convention Cooperation Scheme, Section 9.5.3

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