



## Under pressure

DPTE<sup>®</sup> Transfer Leak Tester (TLT)  
secures compliance and integrity

# Transfer Leak Tester (TLT)

## Wireless and pipeless for DPTE® Alpha and Beta parts

### Meet current and future regulations

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 Beta parts using pressure with reliable and accurate repeatability.



### Getinge's 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.

- Full traceability compliant to FDA 21 CFR part 11 and EU Annex 11
- A modern tool compliant to international guidelines\*
- Wireless, paperless and pipeless (no cables and pipes between the remote head and the main unit)
- Based on pressure decay method according to ISO Guidelines
- Simple and easy to apply on both Alpha and Beta assemblies, both PE and stainless steel



- Compatible with all rigid DPTE® Alpha and Beta parts on the market (105 - 350 mm)
- HMI available either with external tablet or with onboard version, integrated (through SCADA) for Getinge isolators

\* 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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