

## DPTE® sterile transfer solutions

# Secure requalification with the DPTE® System

The Original DPTE® System from Getinge is the world's leading sterile transfer solution. A fully validated system, DPTE® enables you to efficiently secure requalification in your production. Here's a breakdown of the advantages:

### Reduce manual intervention in your production

The DPTE® System is designed to minimize the need for manual intervention – the major cause of microbial and particulate contamination in aseptic process. This process helps to streamline the requalification process, frees up operators' time for other tasks, minimizes delays, and reduces the risk of accident or injury.



**Minimize contamination**



**Increase productivity**



**Improve safety**

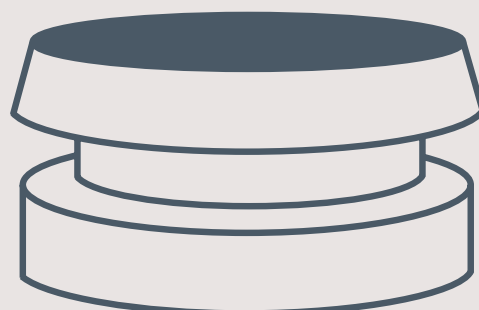
### Avoid the risks



- Contamination of aseptic core
- Damaged equipment
- Unexpected downtime
- Danger to Operator safety

### DPTE® Transfer Leak Tester TLT

The TLT is a smart, ergonomic tester plug that fastens easily to both DPTE® Alpha and DPTE® rigid Beta parts. It supports a preventive maintenance program. Check the leaktightness of your system before and after production batches to ensure that your processes are compliant to international standards and regulations.



- **Wireless and pipeless**
- **Fully traceable**
- **Easy to use**



- **Secure compliance**
- **Ensure safety**
- **Maximize cost-efficiency**



- **FDA 21 CFR Part 11**
- **GAMP 5**

### DPTE® System validation

Support requalification of your installed base – DPTE® systems, Alpha and Beta, guaranteeing product and patient safety. The TLT solution is aligned with recommendations to perform integrity testing regularly as stated by the following guidelines:

- Annex 1 to EU GMP: Manufacture of Sterile Medicinal Products
- FDA Aseptic Processing Guidance: Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice
- PIC/S Pharma Inspection Convention Cooperation Scheme