

## Regulatory requirements

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- FDA and cGMP compliant
- Compliant with GAMP 5, CFR 21 Part 11, EU GMP Annex 1 and Annex 11
- MK can help you to meet the Annex 1 leak testing requirements with minimum impact to your production schedule: Integrity testing of the barrier systems, (...) performed minimum at the beginning and end of each batch is possible in an easy and fast way
- Easy integration into existing GITS® 4 software



## Contact us

**MK METALFREE**

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[www.mk-metalfree.com](http://www.mk-metalfree.com)



## Fully automatic Transfer System Tester

**MK TST Alpha**  
**MK TST Beta**

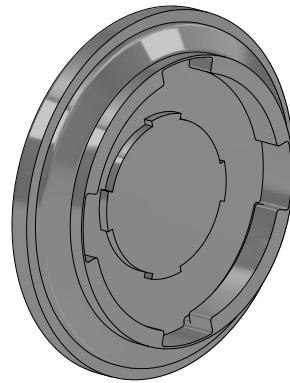
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Your solution to meet EU GMP  
Annex 1 requirements

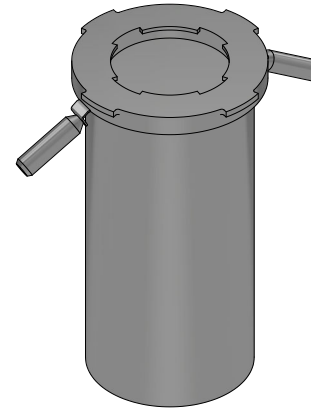


## Easy to use

### 1 TST Alpha Port

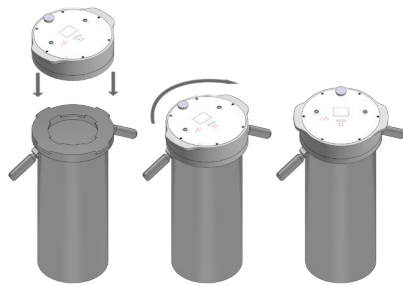


Alpha Port

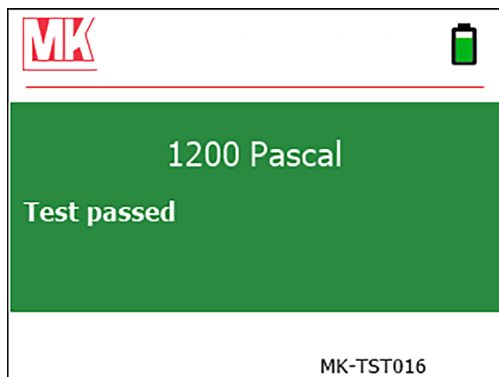


Beta Container

### 2 TST Beta Container



### 3 Start measurement



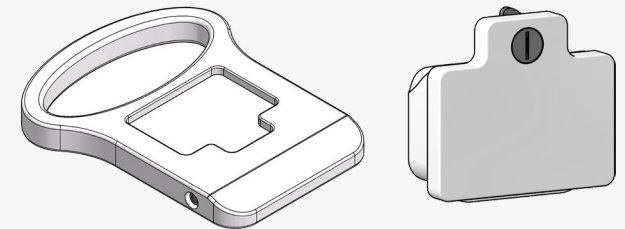
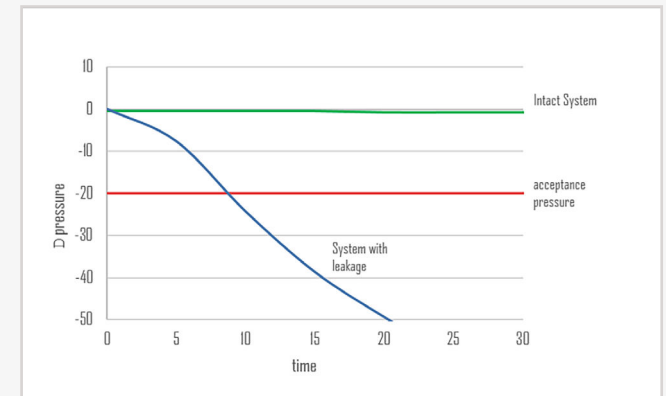
## Features

- Integrated in your existing GITS® 4 system
- Integrated WLAN functionality and optional RFID recognition
- Administration of recipe parameters and users
- Creation of PDF measurement reports
- Integration into product life cycle tracking via GLCS® software
- MES and SCADA integration possible

## Accessories and services

- Specific test parameters
- Qualification services (IQ, OQ, PQ and more)
- Service and maintenance
- WLAN site survey and planning

## Parameter development



- Inductive battery (incl.) and charging station