

## Annex 1 guidelines

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- Integrity testing of barrier systems
- Leak testing of glove systems and the isolator at defined periods, at a minimum at the beginning and end of each batch
- We offer pressure decay tests for Gloves, Alpha ports, Beta containers and Half-suits
- The frequency of glove replacement should be defined within the Contamination Control Strategy (CCS)
- With GITS4 and GLCS3 you meet all requirements of Annex 1 and collect all data relevant for defining the CCS

## Integrity testing for barrier systems

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- Gloves
- Alpha ports
- Beta containers
- Half-suits
- Compliant to latest ANNEX 1 guidelines
- FDA-accepted and cGMP compliant



## EU GMP Annex 1 Manufacture of sterile medicinal products

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Do you meet the Annex 1 requirements?  
We provide the solution!

Integrity testing for barrier systems.



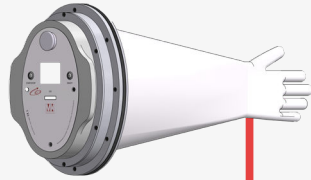
Contact us

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MK Glove Test Device  
Generation 3



Traceability with RFID  
chipped gloves



MK Transfer System  
Tester



Features to comply with

Annex 1



Traceability with RFID  
chipped glove ports



Glove Integrity Test System



Glove Life Cycle System



MK software runs on any  
Windows® system



Analysis and  
Reporting Tool