

Annex 1 guidelines

- 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

- 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

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

Integrity testing for barrier systems.



Contact us

MK Versuchsanlagen GmbH & Co. KG

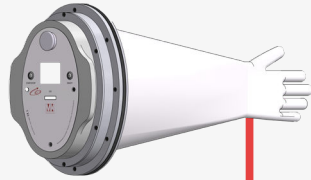
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MK Glove Test Device Generation 3



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