

DESIGN, VALIDATION AND MONITORING OF STERILIZATION-PROCESSES AND -INSTRUMENTS



Accredited by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-P-403.07.07

Summary of Test Report

SAL-GmbH is an accredited test laboratory according EN ISO 17025 from ZLG Germany.

We have made a test report no. 082068 checking the product manufactured and delivered from gke-GmbH, Germany, Auf der Lind 10, 65529 Waldems:

Art.-No.	Name	Description
211-150	Chemo-D-BDS-1-C-H-EU	Starter kit Bowie-Dick-Simulation-Test with Compact-PCD, colour: blue, validated according EN 867-4

Above product has been tested. The same product is available as process challenge device and refill packs separately:

Art.-No.	Name	Description
211-151	Chemo-D-BDS-1-C-H-EU	Replacement PCD Bowie-Dick-Simulation-Test, colour: blue
211-111	Chemo-D-BDS-1	Refill pack for Bowie-Dick-Simulation-Test (100, 250, 500 indicator strips)
211-112	Chemo-D-BDS-2,5	
211-115	Chemo-D-BDS-5	

Test results:


The above mentioned Bowie-Dick-Simulation-Test is an indicator of class 2 according to EN ISO 11140-1 and fulfills all requirements for a Bowie-Dick cotton pack described in EN 285. Equivalence is tested with the B1 reference cycle according to EN ISO 11140-4. The test device cannot be tested in the test cycles B2 and B3 since those cycles are unable to remove the air from that test system. As a result the test device exceeds the requirements for air removal and steam penetration according to the standard reference Bowie-Dick cotton pack.


In addition the above mentioned Bowie-Dick-Simulation-Test fulfills all requirements for the test system in steam sterilization processes described in the European standard EN 867-5 "Hollow A" to the full extent and exceeds the air removal sensitivity of the above mentioned reference test device "Hollow A" in fractionated vacuum cycles.

The additional "Hollow A" test has been integrated in the European standard for steam sterilizers EN 285:2008 as an additional type test.

If another process challenge device (PCD) or indicator strips (indicator systems) than the one described above is used, the test results are not comparable and this test report is not valid.

Glashütten, 2009-01-09


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