

Operator: John Doe Vessel: No. X  
 Process: Demo Product: Steam Autoclave  
 Session Start: 03-04-2008 12:39:02 Time Zone: Rom, normaltid (UTC offset 01:00:00)  
 Session Stop: 03-04-2008 14:18:47  
 Session Name: Demo  
 Session Text: Prog. 1: 134 °C / 8 min. / pulse vacuum drying



## Validation Report

**Total Test Result** **Passed**

Name: Validation Report  
 Description: Steam sterilization  
 Cycle:

### Input Parameters

Process Temperature : 134.00 °C  
 Process Temperature Band (K): 3.00  
 Maximum Temperature Fluctuation (K): 1.00  
 Maximum Temperature Difference (K): 2.00  
 Maximum Equilibration Time: 00:00:30  
 Minimum Holding Time: 00:03:00  
 Maximum Pressure Deviation: 0.1000 bar

### Equilibration Time

Equilibration Start Time: 03-04-2008 13:12:46  
 Equilibration End Time: 03-04-2008 13:12:46  
 Equilibration Duration: 00:00:00  
 Max. allowed Equilibration Duration: 00:00:00  
 Equilibration Test Result: Passed

### Process band

Holding Start Time: 03-04-2008 13:12:46  
 Holding End Time: 03-04-2008 13:21:21  
 Holding Duration: 00:08:35  
 Min. allowed Holding Duration: 00:03:00  
 Holding Test Result: Passed

### Homogeneous Band

Homogeneous Temperature (K): 0.05  
 Max. Allowed Homogeneous Temperature (K): 2.00  
 Homogeneous Temperature Test Result: Passed

### Fluctuation Band

Temperature Fluctuation (K): 0.86  
 Max. Allowed Temperature Fluctuation (K): 1.00  
 Temperature Fluctuation Test Result: Passed

### Saturated Steam Analysis

Pressure Deviation: 0.0338 bar  
 Max. Pressure Deviation: 0.1000 bar  
 Pressure Deviation Test Result: Passed

### Summary Report

| Name | Fluctuation (°C) | Deviation  |
|------|------------------|------------|
| 1    | 0,82             | 0,0331 bar |
| 2    | 0,84             | 0,0338 bar |
| 3    | 0,83             | 0,0318 bar |
| 4    | 0,84             | 0,0293 bar |

Operator/Date:

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Afløb 0,84 0,0313 bar

**Lethality Calculation:**

Lethality - Max. Pressure Deviation: 0.1000 bar  
 Lethality - Min. Saturated Steam Duration: 00:03:00  
 Lethality - Min. Lethality value: 15.00  
 Lethality - Reference Temperature: 121.11 °C  
 Min. Temperature for Lethality-Calculation: 91.11 °C  
 Lethality - Z-Value: 10 °C

**Individual Analysis**

| Name                            | Lethality Value | Lethality Value Status | Saturated Steam Duration | Saturated Steam Duration Status |
|---------------------------------|-----------------|------------------------|--------------------------|---------------------------------|
| Lethality - 1 (Saturated Steam) | 198,78          | Passed                 | 00:08:35                 | Passed                          |
| Lethality - 1 (Normal)          | 198,78          | Passed                 | N/A                      | N/A                             |
| Lethality - 2 (Saturated Steam) | 199,04          | Passed                 | 00:08:35                 | Passed                          |
| Lethality - 2 (Normal)          | 199,04          | Passed                 | N/A                      | N/A                             |
| Lethality - 3 (Saturated Steam) | 198,12          | Passed                 | 00:08:35                 | Passed                          |
| Lethality - 3 (Normal)          | 198,12          | Passed                 | N/A                      | N/A                             |
| Lethality - 4 (Saturated Steam) | 198,22          | Passed                 | 00:08:35                 | Passed                          |
| Lethality - 4 (Normal)          | 198,22          | Passed                 | N/A                      | N/A                             |
| Lethality - 5 (Saturated Steam) | 198,11          | Passed                 | 00:08:35                 | Passed                          |

Operator/Date: