Microtest

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Testing Certificate Summary

Client: Innovative Medical Products
87 Spring Lane
Plainville, CT 06062

Sample #s: 11-04377/04399 & 11-04402/04403
Date Started: 20Jun11
Date Completed: 30Aug11

Procedures: GLP-11-182/SPN #11-029 rev 000, Pre-Vacuum Steam Sterilization Dry Time Validation
GLP-11-187/SPN #11-030 rev 000, Pre-Vacuum Steam Sterilization Validation
GLP-11-188/SPN #11-032 rev 000, Pre-Vacuum Steam Sterilization Dry Time Validation
GLP-11-189/SPN #11-033 rev 000, Pre-Vacuum Steam Sterilization Validation

Sample Description: 706-S case with 803-BP, DeMayo Knee Positioner Base and 706-L case with 803-ABD aluminum boot, 903 Single Level Clamp, and 907 Distractor

Dry Time Results Summary:

Table I: 706-S CSR Wrap Weights and Visual Assessment

Run Number	Dry Time	Cycle Parameters	CSR Wrap Weight Before	CSR Wrap Weight After	Percent Weight Gain	Visual Moisture (yes/no)	Pass/Fail
1	20 Minutes	Pre-Vacuum, 132°C, 4.0 minute exposure, double wrapped in CSR	158.0g	156.0g	-1.3%	No	Pass

Table II: 706-L Case CSR Wrap weights and Visual Assessment

Run Number	Dry Time	Cycle Parameters	CSR Wrap Weight Before	CSR Wrap Weight After	Percent Weight Gain	Visual Moisture (yes/no)	Pass/Fail
1	20 Minutes	Pre-Vacuum, 132°C, 4.0 minute exposure, double wrapped in CSR	206.5g	203.0g	-1.7%	No	Pass

Sterilization Results Summary:

Table I: 706-S Case Sterilization Results

Run #	Biological Indicator Strip Sterility Failures	Cycle Parameters	Minimum 6 log reduction for 3 consecutive runs (Pass/Fail)
1-3	0 of 18	Pre-Vacuum cycle, 132°C, 2 minute exposure (half cycle), 4 pulses, 0.0 minute dry, double layer CSR wrap	Pass

Table II: 706-L Case Sterilization Results

Run #	Biological Indicator Strip Sterility Failures	Device Sterility Failures	Cycle Parameters	Minimum 6 log reduction for 3 consecutive runs (Pass/Fail)
1-3	0 of 15	0 of 6	Pre-vacuum, 4 pulses, 132°C, 2 minute exposure (half cycle), 0.0 minute dry, double layer CSR wrap	Pass

Conclusion:

A dry time of twenty (20) minutes was successfully validated for the four (4.0) minute Pre-vacuum cycle (4 pulses), at 132°C for the Innovative Medical Products (IMP) 706-L case with 803-ABD aluminum boot, 903 Single Level Clamp, and 907 Distractor and the Innovative Medical Products (IMP) 706-S case with 803-BP, De Mayo Knee Positioner Base.

The results of the Biological Indicators indicated no spore survivors for three consecutive half cycles. The Innovative Medical Products (IMP) 706-L case with 803-ABD aluminum boot, 903 Single Level Clamp, and 907 Distractor and the Innovative Medical Products (IMP) 706-S case with 803-BP, De Mayo Knee Positioner Base was judged to be effectively sterilized at 132°C for 2 minutes Pre-Vacuum half cycle and a zero (0.0) minute dry time.

The cycle conditions are considered adequate to achieve an SAL minimum of 10^{-6} at twice the stated exposure time. The thermocouples passed the verification calibration. All positive and negative controls were satisfactory.

Study Director

22 Sep 11
Date