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RE: Dr. Brown's Medical Letter of Validation to Support Steam Sterilization (Autoclaving)

The information below addresses the effectiveness of Steam Sterilization (Autoclaving) for Dr. Brown's® bottle systems, which include a vessel, insert, reservoir, nipple, collar, cap, and, when applicable, infant-paced feeding valve.

The test was required to ensure the functionality of the bottle system would tolerate a total of 30 autoclaving cycles and eradicate highly moist-heat resistant microbes when used according to the required steam sterilization and drying guidelines.

The mechanisms for obtaining the results were the following:

1. The test method acceptance criteria were performed in accordance with the guidance document.
2. The protocol was in line with all decontamination protocols including the guidelines for use with normal steam sterilization (autoclaving) process.

Steam Sterilization Repeat Exposure Testing Set Points

Sterilizer Type Pre-Vacuum

Preconditioning Pulses 3

Temperature 270°F/132°C

Full Cycle Exposure Time 04 minutes 00 seconds

Dry Time 30 minutes 00 seconds

Test Article Configuration Individually single pouch each test article and place on edge in sterilizer

3. Calculations for the reduction in bacterial counts were calculated using the following formula:

$$\% \text{ Reduction} = 100 - (\text{Final Population} / \text{Initial Population} \times 100)$$

Results –

1. Testing revealed the functionality of Dr. Brown's bottle system was not compromised up to 30 cycles of steam sterilization if sterilized according to the parameters above.
2. The decontamination final report revealed \geq to 99.99% eradication of a highly moist-heat resistant microbe (*Geobacillus stearothermophilus*) when used according to normal steam sterilization and drying guidelines.

Thank you for allowing us the opportunity to share our findings with you. Dr. Brown's Medical is pleased with the outcome of the test and looks forward to conducting business with you and your facility.

Sincerely,

Sandra J. Aubuchon

Sandra J. Aubuchon

President, Dr. Brown's Medical

Dr. Brown's Company

4433 Fyler Ave.

St. Louis, MO 63116

314.445.3310

sandi.aubuchon@drbrownsmedical.com

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