

CERTIFICATE OF ANALYSIS

 FOR SINGLE USE IN PRE-VACUUM **STEAM** STERILIZERS

This lot of product meets the accepted performance criteria recommended in ISO 11140-1: 2014 for Type 2 Indicators and former EN 867-4 Class B standards.

LOT 22156

REF BD-1X


2023-08

Indicating Ink Origin of Manufacture: United States



2018-08

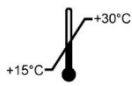





Indications for Use: 134°C for 3.5 minutes or 121°C for 15 minutes

Performance Requirements

Requirement	Specification	Result
Color Transition with Effective Vacuum (3.5 Minutes at 134°C or 15 Minutes at 121°C)	Blue to Pink	Pass
Date of Product Performance Verification:	August 2018	

Color Transition is dependent upon sterilizer size, type, vacuum depth and may vary. A color transition from the initial colour blue to a shade of the signal colour which is uniformly pink indicates effective steam penetration. If color transition is not uniform or a purple-violet colour is achieved, check cycle parameters and equipment function.

Shelf Life and Storage

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep dry
	Don not re-use; Single use only		Keep away from sterilants; Do not use after expiration date

QUALITY APPROVAL _____

Date _____