



TRUE **INDICATING**  
PRODUCTS

## VALIDATION REPORT

### TEST LOCATION

True Indicating Products  
946 Kane Street, Suite A  
Toledo Ohio 43612

### ISO 11140-1:2014 Compliance Determination

Inpoint Medicare Sterilization Pouches, Rolls and Strips Integrator for Steam

Type 5 Integrator for Steam



TRUE **INDICATING**  
PRODUCTS

## VALIDATION REPORT

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3-26-19

Date

Approved By:

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3-26-19

Date



## 1. Introduction

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The purpose of the study was to determine if the Inpoint Medicare Sterilization Pouches, Rolls with internal and external indicators and Type 5 Integrator strips was compliant as a Type 5 Integrator per 11140-1:2014 Sterilization of health care products - Chemical indicators Part 1: General requirements. Meeting ISO compliance for this standard is indicative of meeting the requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical changes of substances, and which are used to monitor the attainment of one or more of the process parameter(s) specified by the standard for a given sterilization process. An integrating indicator is designed to react to all critical process parameters, including time, temperature and moisture for steam processes. The Stated Values (SVs) are generated to be equivalent to, or exceed, the performance requirements outlined in the ISO 11138-series for Biological Indicators and demonstrate how the indicator integrates over the temperature range.

ISO 11140-1:2014 specifies performance requirements and/or test methods for chemical indicators intended for steam requiring SVs at 121°C and 135°C and at one or more equally spaced temperature points in that range. An integrating indicator shall have a determined temperature coefficient from the slope of the curve created by plotting the log SV versus the temperature. Further, integrating indicators for steam shall be evaluated in dry heat conditions.

## 2. Materials & Equipment

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- A. One lot of Inpoint Medicare Sterilization Pouches, Rolls and Strips supplied by the manufacturer
- B. Steam Resistometer (ID: 1000)
- C. Dry Heat Resistometer (ID: 1026)

## 3. Method

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- 1. One lot of Inpoint Medicare Sterilization Pouches/Rolls/Strips was provided by the manufacturer.
- 2. The physical appearance was observed and recorded prior to testing.
- 3. Individual sections of the sterilization product containing a steam indicator were separated and heat sealed into small pouch sections prior to exposure. Three separate steam indicators were exposed per each exposure condition outlined in Table 1 using a steam resistometer, and a dry heat resistometer.
- 4. The initial and signal color was inspected for each indicator exposed, exposure results were summarized in Table 2 and photographed with a side by side comparison of all exposures outlined in Appendix A.

All exposed indicators were retained with the raw data.

- 5. ISO 11140-2014 compliance was assigned based on the obtained exposure results.



4. Acceptance Criteria

**Table 1: Performance Requirements for Type 5 Integrating Indicators for Steam**

Test Environment	Test Time	Test Temperature	No change or a change that is markedly different from the visible change as specified by the manufacturer	Visible Change as specified by the manufacturer
Steam Stated Value (SV)	16.5 minutes	121°C	Unacceptable result	Acceptable result
Steam Failure	14.0 minutes	120°C	Acceptable result	Unacceptable result
Steam SV	3.3 minutes	128°C	Unacceptable result	Acceptable result
Steam Failure	2.8 minutes	127°C	Acceptable result	Unacceptable result
Steam SV	1.2 minutes	135°C	Unacceptable result	Acceptable result
Steam Failure	1.0 minutes	134°C	Acceptable result	Unacceptable result
Dry Heat	30 minutes	140°C	Acceptable result	Unacceptable result
<b>Integrating Indicator Temperature Coefficient</b>				
10°C – 27°C				
<b>Correlation Coefficient</b>				
≥ 0.9				

Test Environment	Test Time	Test Temperature	No change or a change that is markedly different from the visible change as specified by the manufacturer	Visible Change as specified by the manufacturer
Steam Stated Value (SV)	3.5 minutes	134°C	Unacceptable result	Acceptable result
Steam Failure	3 min, 17 sec.	133°C	Acceptable result	Unacceptable result
Dry Heat	30 minutes	140°C	Acceptable result	Unacceptable result





5. Results

Table 2: Test Results for Type 5 Integrating Indicators for Steam

Test Environment	Test Time	Test Temperature	Exposure Color Results
Steam SV Cycle # 573	16.5 minutes	121°C	Acceptable result Visible change.
Steam Failure Cycle # 574	14.0 minutes	120°C	Acceptable result Markedly different than the visible change.
Steam SV Cycle # 580	3.3 minutes	128°C	Acceptable result Visible change.
Steam Failure Cycle # 581	2.8 minutes	127°C	Acceptable result Markedly different than the visible change.
Steam SV Cycle # 583	1.2 minutes	135°C	Acceptable result Visible change.
Steam Failure Cycle # 584	1.0 minutes	134°C	Acceptable result Markedly different than the visible change.
Dry Heat Cycle # 190221-01	30 minutes	140°C	Acceptable result No change.
Result			
Integrating Indicator Temperature Coefficient			12.3°C
Correlation Coefficient			0.98180531

Test Environment	Test Time	Test Temperature	Exposure Color Results
Steam SV Cycle # 586	3.5 minutes	134°C	Acceptable result Visible change.
Steam Failure Cycle # 587	3 min, 17 sec.	133°C	Acceptable result Markedly different than the visible change.
Dry Heat Cycle # 190222-01	30 minutes	140°C	Acceptable result Markedly different than the visible change.



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## 6. Conclusion

All acceptance criteria were met for Inpoint Medicare Sterilization Pouches , Rolls and Strips Steam Indicators as a Type 5 Integrating Indicator for steam using exposures within the range of 121°C - 135°C.

Based upon the observed and recorded results, the Inpoint Medicare Sterilization Pouch , Roll and Strips Steam Indicator was determined to meet the standards set per ISO 11140-1:2014 as a Type 5 Integrator for steam.

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## 7. Records

All raw data pertaining to this study and a copy of the final report was stored in a designated archive file.



8. Appendix A – Comparison of Exposure Colors

Stated Value (SV)	Indicator Type	Initial Color	Steam Fail Color	Steam Signal Color	Dry Heat Exposure
121°C 16.5 min	Blue Film Removed				
	Blue Film Present				
	Strip				
128°C 3.3 min	Blue Film Removed				
	Blue Film Present				
	Strip				
135°C 1.2 min	Blue Film Removed				
	Blue Film Present				
	Strip				





Stated Value	Indicator Type	Initial Color	Steam Fail Color	Steam Signal Color	Dry Heat Exposure
134°C 3.5 min	Blue Film Removed				
	Blue Film Present				
	Strip				