

Class	ISO11140 - 1: 2005 Definition*	Practical Application
<p><b>Class 1:</b> <b>Process Indicators</b></p>	<p>Process indicators are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designed to react to one or more of the critical process variables</p>	<p>Indicator tapes, indicator labels, and load cards are examples of externally visible Chemical Indicators that are Process Indicators used for exposure control.</p>
<p><b>Class 2:</b> <b>indicators for use in specific tests</b></p>	<p>Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards.</p>	<p>Bowie-Dick type tests are specific tests used for equipment control to evaluate the sterilizer performance.</p>
<p><b>Class 3:</b> <b>Single variable indicators</b></p>	<p>A single variable indicator shall be designed to react to one of the critical variables and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable.</p>	<p>An example of a Single Variable Indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature. Single variable indicators may be used for pack control monitoring but would not provide as much information as a Class 4 or Class 5 Chemical Indicator. Single Variable Indicators may also be used for exposure control monitoring. This temperature tube would be used to determine that a specific temperature was reached at a specific location in the steriliser chamber.</p>
<p><b>Class 4:</b> <b>Multi-variable indicators</b></p>	<p>A multi-variable indicator shall be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilisation process at the stated values (SVs) of the chosen variables.</p>	<p>Multi-variable Chemical Indicators are used for pack control. These internal Chemical Indicators are usually paper strips printed with a Chemical Indicator.</p>
<p><b>Class 5:</b> <b>Integrating indicators</b></p>	<p>Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO 11138 series for BIs .</p>	<p>Integrating Indicators are the most accurate of the internal Chemical Indicators. Integrating Indicators are used for pack control monitoring. They can also be used as an additional monitoring tool.</p>
<p><b>Class 6:</b> <b>Emulating indicators</b></p>	<p>Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilisation process.</p>	<p>Emulating Indicators can be used as internal Chemical Indicators for pack control. Emulating Indicators are specified for specific sterilisation cycles which means an end user will need to inventory a different Class 6 Emulating Indicator for each sterilisation cycle time and temperature (e.g. 3 min and 15 min) run in the facility. The response of a Class 6 Emulating Indicator does not necessarily correlate to a Biological Indicator.</p>