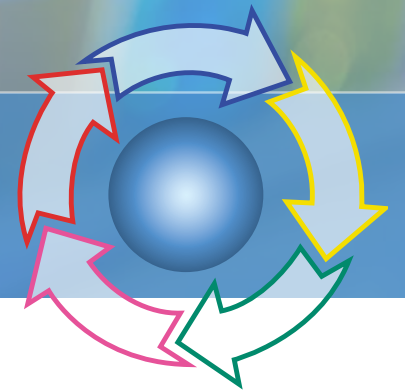


3M™ Sterilisation



Steam Chemical Indicator Classifications





Background:

In 1995 ISO (International Organisation for Standardisation) published ISO 11140-1:1995 Sterilization of healthcare products – Chemical indicators – Part 1: General requirements. In 1997 CEN (Comité Européen de Normalisation) published the EN 867 series on the same subject, “non-biological” or “chemical” indicators. One of the major differences was that the European norm defined 4 classes (A, B, C and D) of chemical indicators and the ISO standard defined 6 (1 to 6). In order to overcome this annoying situation of double standards, CEN and ISO agreed on a joined revision under the so-called Vienna Agreement.

In 2005, the updated ISO 11140 - 1 standard was published and approved by the CEN. The new document is EN ISO 11140-1, 2005 Sterilization of health care products – Chemical indicators – Part 1: General requirements.

Key Learnings:

For Steam Chemical Indicators;

- **Classes have NO hierarchical significance. Each class has its own characteristics and intended use**
- **In ISO 11140 - 1: 2005, Class 5 Integrating Indicator performance requirements were strengthened to ensure performance is comparable to Biological Indicators in saturated steam. As a result, Class 5 Integrating Indicators are the most accurate of the internal Chemical Indicator classes when compared to the performance of Biological Indicators**
- **Class 6 Emulating Indicators are now a recognized Chemical Indicator classification in ANSI/AAMI/ISO 11140 - 1, 2005 Sterilization of health care products–Chemical indicators–Part 1: General requirements**
- **Your choice of Chemical Indicator class should be based on the information you need about a particular sterilization process**



Steam Chemical Indicators defined:

The ISO11140 - 1:2005 document defines six classes of Chemical Indicators (see table on last page). It is of importance to recognize that the class definition is not hierarchical. This is emphasized in clause 4 of the ISO 11140 - 1:

« ...

4. Classification

4.1 General

In subsequent parts of ISO 11140, indicators are classified by their intended use. The chemical indicators described in this part of ISO 11140 are classified into six groups. The chemical indicators within each of these classifications are further subdivided by the sterilization process for which they are designed to be used. The classification structure used is solely to denote the characteristics and intended use of each type of indicator when used as defined by the manufacturer. This classification has no hierarchical significance.

... »

This means that the class number does not mean that one class is necessarily better or measures more parameters of the sterilization process than another class. Class 2 Chemical Indicators probably provide the most information about the sterilization process. Class 3 indicators are not necessarily better than Class 2 indicators, Class 6 indicators are not necessarily better than Class 4, and so on. In addition, a Chemical Indicator should only be labeled as complying with one Class because the required performance characteristics of the classes are distinctly different.

It is important to understand the classes of Chemical Indicators so that you can choose the correct Chemical Indicator for the sterilization process being monitored. Your choice should be based on the information you need about a particular sterilization process.

Summary:

What do the Chemical Indicator classifications mean to the end user?

Chemical Indicator classifications enable the end user to understand performance parameters and tolerances of various Chemical Indicators. The appropriate Chemical Indicator can then be used to obtain the information needed to determine the effectiveness of the sterilization process.

For more information on the ISO 11140 - 1:2005, please contact



Class	ISO11140 - 1: 2005 Definition*	Practical Application
Class 1: Process Indicators	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	Indicator tapes, indicator labels, and load cards are examples of externally visible Chemical Indicators that are Process Indicators used for exposure control.
Class 2: indicators for use in specific tests	Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards.	Bowie-Dick type tests are specific tests used for equipment control to evaluate the sterilizer performance.
Class 3: Single variable indicators	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>An example of a Single Variable Indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature.</p> <p>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.</p> <p>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 sterilizer chamber.</p>



Class	ISO11140 - 1: 2005 Definition*	Practical Application
Class 4: Multi-variable indicators	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 sterilization process at the stated values (SVs) of the chosen variables.	Multi-variable Chemical Indicators are used for pack control. These internal Chemical Indicators are usually paper strips printed with a Chemical Indicator.
Class 5: Integrating indicators	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 .	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.
Class 6: Emulating indicators	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 sterilization process.	Emulating Indicators can be used as internal Chemical Indicators for pack control. Emulating Indicators are specified for specific sterilization cycles which means an end user will need to inventory a different Class 6 Emulating Indicator for each sterilization 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.

* definition out of the ISO11140 - 1, 2005, Sterilization of health care products – Chemical indicators – Part 1: General requirements.

