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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 32310-2015

**Sterilization of health care products -- Chemical indicators --
Guidance for selection, use and interpretation of results**

医疗保健产品灭菌 化学指示物 选择、使用和结果判断指南

(English Translation)

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

This standard uses the translation method identical with ISO 15882:2008 "Sterilization of health care products - Chemical indicators selection, use and knot If the judge's Guide. " this standard made the following editorial changes.

--- According to GB/T 1.1 requirements of a number of editorial changes;

--- Deleted international standards foreword;

--- Standard texts and part of the international standard reference appearing replace the corresponding country standards.

Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of

these patents.

This standard was proposed by the China Food and Drug Administration.

This standard by the National Standardization Technical Committee disinfection technology and equipment (SAC/TC200) centralized.

This standard was drafted. State Food and Drug Administration Guangzhou Medical Device Quality Supervision and Inspection Center, Beijing Science and Technology Co., Hoagy Italy Company, Beijing Medical Device Testing.

1 Scope

1.1

standard chemical indicators of the selection, use and results provide guidelines judgment, these chemical indicators used in the definition of the sterilization process, Confirmation and routine monitoring and overall control. This standard chemical indicators by physical and/or chemical change in the substance to display its violent Exposed to the sterilization process, the sterilization process for monitoring one or more variables. These chemical indicators are not dependent on the survival of living organisms or inactivated.

1.2

This standard does not apply to physical removal indicator microorganisms (such as filters) in the process of being used.

1.3

This standard does not apply to the combination process [for example, the cleaning and disinfection or line cleaning (CIP) and online sterilization (SIP) of the composition process] the indicator used.

2 Terms and definitions

The following terms and definitions apply to this document.

NOTE: ISO/T S11139 [11] provides a set of terms and definitions of health care products sterilization.

Chemical indicators chemicalindicator Non-biological indicators non-biologicalindicator Depending on the chemical or physical change in exposure to a sterilization process produced, showing a plurality of predetermined changes in process variables or tests system.

[ISO/T S11139.2006, the definition 2.6] 2.2 Endpoint Observable change point defined by the manufacturer of the indicator after exposure to a predetermined calibration value appears.

[GB 18282.1-2015, the definition 3.3] 2.3 Indicator Indicator to its final application substrate to form a combination.

[GB 18282.1-2015, the definition 3.5]

Note 1: The composition indicator system and special test load is also defined as the indicator.

Note 2: Appendix E.

Indicator indicatoragent; indicatorreagent Combination of active substance or active substances.

[GB 18282.1-2015, the definition 3.6] Note. See Appendix E.

Process challenge device processchallengeddevice; PCD Constituted of a specific resistance of the sterilization process means for evaluating the performance of the sterilization process.

[ISO/T S11139.2006, definitions 2.33]