

ISO 11140-1:2014-11 (E)

Sterilization of health care products - Chemical indicators - Part 1: General requirements

| Contents | | Page |
|--------------------|---|-------------|
| Foreword | | v |
| Introduction | | vi |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 2 |
| 4 | Categorization | 4 |
| 4.1 | General | 4 |
| 4.2 | Type 1: process indicators | 4 |
| 4.3 | Type 2: indicators for use in specific tests | 5 |
| 4.4 | Type 3: single critical process variable indicators | 5 |
| 4.5 | Type 4: multicritical process variable indicators | 5 |
| 4.6 | Type 5: integrating indicators | 5 |
| 4.7 | Type 6: emulating indicators | 5 |
| 5 | General requirements | 5 |
| 6 | Performance requirements | 8 |
| 6.1 | General | 8 |
| 6.2 | Type 1 indicators | 9 |
| 6.3 | Type 2 indicators | 9 |
| 6.4 | Types 3, 4, 5 and 6 indicators | 9 |
| 7 | Test methods | 9 |
| 7.1 | General | 9 |
| 7.2 | Off-set (transference) | 9 |
| 7.3 | Procedure -- Steam indicators | 9 |
| 7.4 | Procedure -- Dry heat indicators | 10 |
| 7.5 | Procedure -- EO indicators | 10 |
| 7.6 | Procedure -- Low temperature steam and formaldehyde indicators | 11 |
| 7.7 | Procedure -- Vaporized hydrogen peroxide indicators | 11 |
| 8 | Additional requirements for process (Type 1) indicators | 12 |
| 8.1 | Process indicators printed or applied on to packaging material | 12 |
| 8.2 | Process indicators for steam sterilization processes | 12 |
| 8.3 | Process indicators for dry heat sterilization processes | 12 |
| 8.4 | Process indicators for ethylene oxide sterilization processes | 13 |
| 8.5 | Process indicators for radiation sterilization processes | 13 |
| 8.6 | Process indicators for low temperature steam and formaldehyde sterilization processes | 14 |
| 8.7 | Process indicators for vaporized hydrogen peroxide sterilization processes | 14 |
| 9 | Additional requirements for single critical process variable (Type 3) indicators | 15 |
| 10 | Additional requirements for multicritical process variable (Type 4) indicators | 15 |
| 11 | Additional requirements for steam integrating (Type 5) indicators | 16 |

| | | |
|----|--|----|
| 12 | Additional requirements for ethylene oxide integrating (Type 5) indicators | 17 |
| 13 | Additional requirements for emulating (Type 6) indicators | 17 |
| | Annex A (normative) Method for demonstrating shelf-life of the product | 19 |
| | Annex B (informative) Examples of testing indicators | 20 |
| | Annex C (informative) Rationale for the requirements for integrating indicators and the link to the requirements for biological indicators specified in ISO 11138 (all parts) and microbial inactivation | 22 |
| | Annex D (informative) Rationale for the liquid-phase test method for low temperature steam and formaldehyde indicators | 29 |
| | Annex E (informative) Relationship of indicator and indicator system components | 30 |
| | Bibliography | 31 |