

DIN EN ISO 11140-6:2023-02 (E)

Sterilization of health care products - Chemical indicators - Part 6: Type 2 indicators and process challenge devices for use in performance testing for small steam sterilizers (ISO 11140-6:2022)

| Contents | Page |
|---|-------------|
| European foreword | 3 |
| Foreword | 4 |
| Introduction | 5 |
| 1 Scope | 6 |
| 2 Normative references | 7 |
| 3 Terms and definitions | 7 |
| 4 Requirements | 8 |
| 4.1 General..... | 8 |
| 4.2 Porous devices..... | 8 |
| 4.2.1 Reference porous device (RPD)..... | 8 |
| 4.2.2 Detector for reference porous device (RPD)..... | 9 |
| 4.2.3 Alternative porous indicator system (APIS)..... | 10 |
| 4.2.4 Reference porous device (RPD) response..... | 11 |
| 4.3 Hollow devices..... | 11 |
| 4.3.1 Reference hollow device (RHD)..... | 11 |
| 4.3.2 Detector for reference hollow device (RHD)..... | 12 |
| 4.3.3 Reference hollow indicator system (RHIS)..... | 13 |
| 4.3.4 Reference hollow indicator system (RHIS) performance determination..... | 13 |
| 4.3.5 Leakage test..... | 14 |
| 4.4 Alternative hollow indicator system (AHIS)..... | 14 |
| 4.4.1 General..... | 14 |
| 4.5 Alternative hollow devices intended for multiple use..... | 15 |
| 4.6 Test procedure for validation of conformance of the alternative hollow device to the reference hollow device (RHD)..... | 17 |
| 5 Chemical indicator dry heat performance | 18 |
| 5.1 General..... | 18 |
| 5.2 Test 1..... | 18 |
| 5.3 Test 2..... | 19 |
| 6 Marking and labelling | 19 |
| 6.1 Device labelling..... | 19 |
| 6.2 Additional labelling requirements for hollow devices..... | 19 |
| 6.3 Chemical indicators for use in hollow devices..... | 20 |
| Annex A (normative) Test method for performance of reference hollow indicator system (RHIS) | 21 |
| Annex B (normative) Test method for performance of alternative porous indicator system (APIS) | 29 |
| Annex C (normative) Test method for performance of alternative hollow indicator system (AHIS) | 32 |
| Annex D (informative) Relationship between chemical indicator components | 33 |
| Annex E (normative) Reference hollow device (RHD) | 34 |
| Annex F (informative) Accelerated ageing of test samples | 36 |
| Annex G (informative) Evaluation of reference hollow devices (RHDs) — Interlaboratory results | 37 |
| Bibliography | 44 |