

ISO 11138-2:2017-03 (E)

Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

| Contents | | Page |
|---|--|-------------|
| Foreword | | iv |
| Introduction | | v |
| 1 Scope | | 1 |
| 2 Normative references | | 1 |
| 3 Terms and definitions | | 1 |
| 4 General requirements | | 1 |
| 5 Test organism | | 1 |
| 6 Suspension | | 2 |
| 7 Carrier and primary packaging | | 2 |
| 8 Inoculated carriers and biological indicators | | 2 |
| 9 Population and resistance | | 2 |
| Annex A (normative) Method for determination of resistance to ethylene oxide sterilization | | 4 |
| Annex B (informative) Rationale for the inclusion of a second minimum D value specification as a result of changes to the test gas used to evaluate resistance and deletion of the requirement for a minimum D value at 30 °C | | 5 |
| Bibliography | | 6 |