

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