

ISO 11138-5:2017-03 (E)

Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde 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	2
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 low-temperature steam and formaldehyde	4
Annex B (informative) Rationale for the liquid-phase test method for low-temperature steam and formaldehyde biological indicators	6
Bibliography	7