

ISO 10993-13:2010-06 (E)

Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices

Contents	Page
Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Degradation test methods	2
4.1 General procedures	2
4.2 Accelerated degradation test	5
4.3 Real-time degradation test in a simulated environment	6
5 Test procedures	6
5.1 General	6
5.2 Initial material characterization	6
5.3 Accelerated degradation test	6
5.4 Real-time degradation test in a simulated environment	9
6 Test report	10
Annex A (informative) Analytical methods	11
Annex B (informative) Environmental stress cracking (ESC) of polymers	12
Bibliography	14