

# ISO 10993-13:2010-06 (E)

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

---

<b>Contents</b>		<b>Page</b>
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