

# ISO 10993-10:2002-09 (E)

## Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		vi
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	General principles -- Step-wise approach .....	3
5	Pretest considerations .....	4
5.1	General .....	4
5.2	Types of material .....	4
5.3	Information on chemical composition .....	4
5.4	Material characterization .....	5
6	Irritation tests .....	5
6.1	In vitro irritation tests .....	5
6.2	Factors to be considered in design and selection of in vivo tests .....	5
6.3	Animal skin irritation test .....	6
6.4	Human skin irritation test .....	10
7	Delayed hypersensitivity tests .....	14
7.1	Choice of test .....	14
7.2	Choice of test sample concentrations .....	14
7.3	Other important factors affecting the outcome of the test .....	14
7.4	Maximization test for delayed hypersensitivity .....	15
7.5	Closed-patch test for delayed hypersensitivity .....	18
8	Key factors in interpretation of test results .....	20
Annex A (normative)	Preparation of materials for irritation/sensitization testing .....	21
Annex B (informative)	Additional irritation tests .....	23
Annex C (informative)	Background information .....	41
Bibliography .....		45