ISO 10993-10:2002-09 (E)

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

Contents

Page

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