ISO 10993-10:2010-08 (E)

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Contents

Page

Foreword iv

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 General principles -- Step-wise approach 4

5 Pretest considerations 4
5.1 General 4
5.2 Types of material 5
5.3 Information on chemical composition 5

6 Irritation tests 6
6.1 In vitro irritation tests 6
6.2 In vivo irritation tests -- Factors to be considered in design and selection of in vivo tests 6
6.3 Animal irritation test 7
6.4 Animal intracutaneous (intradermal) reactivity test 11
6.5 Human skin irritation test 14

7 Skin sensitization tests 15
7.1 Choice of test methods 15
7.2 Murine Local Lymph Node Assay (LLNA) 15
7.3 Guinea pig assays for the detection of skin sensitization 18
7.4 Important factors affecting the outcome of the test 19
7.5 Guinea pig maximization test (GPMT) 20
7.6 Closed-patch test (Buehler test) 23

8 Key factors in interpretation of test results 26

Annex A (normative) Preparation of materials for irritation/sensitization testing 27

Annex B (normative) Special irritation tests 29

Annex C (normative) Human skin irritation test 44

Annex D (informative) In vitro tests for skin irritation 48

Annex E (informative) Method for the preparation of extracts from polymeric test materials 54

Annex F (informative) Background information 57

Bibliography 61