DIN EN ISO 10993-10:2010-12 (E)

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 6

4 General principles -- Step-wise approach 8

5 Pretest considerations 8
5.1 General 8
5.2 Types of material 9
5.3 Information on chemical composition 9

6 Irritation tests 10
6.1 In vitro irritation tests 10
6.2 In vivo irritation tests -- Factors to be considered in design and selection of in vivo tests 10
6.3 Animal irritation test 11
6.4 Animal intracutaneous (intradermal) reactivity test 15
6.5 Human skin irritation test 18

7 Skin sensitization tests 19
7.1 Choice of test methods 19
7.2 Murine Local Lymph Node Assay (LLNA) 19
7.3 Guinea pig assays for the detection of skin sensitization 22
7.4 Important factors affecting the outcome of the test 23
7.5 Guinea pig maximization test (GPMT) 24
7.6 Closed-patch test (Buehler test) 27

8 Key factors in interpretation of test results 30

Annex A (normative) Preparation of materials for irritation/sensitization testing 31

Annex B (normative) Special irritation tests 33

Annex C (normative) Human skin irritation test 48

Annex D (informative) In vitro tests for skin irritation 52

Annex E (informative) Method for the preparation of extracts from polymeric test materials 58

Annex F (informative) Background information 61

Bibliography 65

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices 72

Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices 73