

DIN EN ISO 10993-10:2023-04 (E)

Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993 -10:2021)

| Contents | Page |
|--|------|
| European foreword | 4 |
| Annex ZA (informative) Relationship between this European standard and the General Safety and Performance requirements of Regulation (EU) 2017/745 aimed to be covered | 5 |
| Foreword | 8 |
| Introduction | 9 |
| 1 Scope | 10 |
| 2 Normative references | 10 |
| 3 Terms and definitions | 10 |
| 4 General principles — Step-wise approach | 12 |
| 5 Pretest considerations | 13 |
| 5.1 General | 13 |
| 5.2 Types of material | 13 |
| 5.2.1 Initial considerations | 13 |
| 5.2.2 Ceramics, metals and alloys | 13 |
| 5.2.3 Polymers | 13 |
| 5.2.4 Biologically derived materials | 13 |
| 5.3 Information on chemical composition | 13 |
| 5.3.1 General | 13 |
| 5.3.2 Existing data sources | 14 |
| 6 Skin sensitization tests | 14 |
| 6.1 Choice of test methods | 14 |
| 6.2 Murine local lymph node assay | 15 |
| 6.2.1 Principle | 15 |
| 6.2.2 Test sample preparation | 15 |
| 6.2.3 Animals and husbandry | 15 |
| 6.2.4 Test procedure | 16 |
| 6.2.5 Treatment groups | 17 |
| 6.2.6 Determination of cellular proliferation and tissue preparation | 17 |
| 6.2.7 Results and interpretation | 18 |
| 6.2.8 Test report | 18 |
| 6.3 Guinea pig assays for the detection of skin sensitization | 18 |
| 6.3.1 Principle | 18 |
| 6.3.2 Choice of test sample concentrations | 19 |
| 6.3.3 Induction | 19 |
| 6.3.4 Challenge | 19 |
| 6.4 Important factors affecting the outcome of the test | 19 |
| 6.5 Guinea pig maximization test | 20 |
| 6.5.1 Principle | 20 |
| 6.5.2 Test sample preparation | 20 |
| 6.5.3 Animals and husbandry | 20 |
| 6.5.4 Test procedure | 21 |
| 6.5.5 Observation of animals | 23 |
| 6.5.6 Evaluation of results | 23 |
| 6.5.7 Test report | 24 |
| 6.6 Closed-patch test (Buehler test) | 24 |
| 6.6.1 Principle | 24 |
| 6.6.2 Test sample preparation | 24 |

| | | |
|---|---|-----------|
| 6.6.3 | Animals and husbandry..... | 24 |
| 6.6.4 | Test procedure..... | 25 |
| 6.6.5 | Observation of animals..... | 26 |
| 6.6.6 | Evaluation of results | 26 |
| 6.6.7 | Test report..... | 26 |
| 7 | Key factors in interpretation of test results..... | 27 |
| Annex A (normative) Preparation of materials for skin sensitization testing..... | | 28 |
| Annex B (informative) Method for the preparation of extracts from polymeric test materials | | 30 |
| Annex C (informative) Non-animal methods for skin sensitization..... | | 33 |
| Annex D (informative) Background information on sensitization tests for skin sensitization..... | | 46 |
| Bibliography..... | | 49 |