

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 (intra-dermal) 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
---	-----------