

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

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

---

<b>Contents</b>		<b>Page</b>
European foreword .....		4
<b>Annex ZA (informative) Relationship between this European standard and the General Safety and Performance requirements of Regulation (EU) 2017/745 aimed to be covered</b> .....		<b>5</b>
Foreword .....		8
Introduction .....		9
<b>1</b>	<b>Scope</b> .....	<b>10</b>
<b>2</b>	<b>Normative references</b> .....	<b>10</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>10</b>
<b>4</b>	<b>General principles — Step-wise approach</b> .....	<b>12</b>
<b>5</b>	<b>Pretest considerations</b> .....	<b>13</b>
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
<b>6</b>	<b>Skin sensitization tests</b> .....	<b>14</b>
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
<b>7</b>	<b>Key factors in interpretation of test results.....</b>	<b>27</b>
	<b>Annex A (normative) Preparation of materials for skin sensitization testing.....</b>	<b>28</b>
	<b>Annex B (informative) Method for the preparation of extracts from polymeric test materials.....</b>	<b>30</b>
	<b>Annex C (informative) Non-animal methods for skin sensitization.....</b>	<b>33</b>
	<b>Annex D (informative) Background information on sensitization tests for skin sensitization.....</b>	<b>46</b>
	<b>Bibliography.....</b>	<b>49</b>