

# DIN EN ISO 10993-23:2026-03 (E)

## Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021 + Amd 1:2025) (includes Amendment A1:2025)

Contents		Page
Foreword		v
<b>A1</b> Foreword to Amendment 1 <b>A1</b>		vi
Introduction		vii
<b>1</b>	<b>Scope</b>	<b>1</b>
<b>2</b>	<b>Normative references</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions</b>	<b>1</b>
<b>4</b>	<b>General principles — Step-wise approach</b>	<b>3</b>
<b>5</b>	<b>Pre-test considerations</b>	<b>4</b>
5.1	General	4
5.2	Types of material	5
5.2.1	Initial considerations	5
5.2.2	Ceramics, metals and alloys	5
5.2.3	Polymers	5
5.2.4	Biologically derived materials	5
5.3	Information on chemical composition	5
5.3.1	General	5
5.3.2	Existing data sources	5
<b>6</b>	<b><i>In vitro</i> irritation tests</b>	<b>6</b>
6.1	General	6
6.2	<i>In vitro</i> reconstructed human epidermis model	6
6.2.1	Test system — Reconstructed human epidermis model	6
6.2.2	Principle of the method	6
6.2.3	Prediction model	7
6.3	Materials	8
6.3.1	Reconstructed human epidermis models — Product description	8
6.3.2	Preparation of medical device extracts	8
6.4	Methods	9
6.4.1	General	9
6.4.2	Test procedure	9
6.4.3	Media and end point solutions	10
6.4.4	Test sample and control preparation	11
6.5	Considerations for test performance	11
6.5.1	Receipt of the reconstructed human epidermis tissues	11
6.5.2	Preparation and pre-incubation	11
6.6	Application of the test sample and rinsing	12
6.6.1	General	12
6.6.2	Preparation	12
6.6.3	Test extract and controls exposure	12
6.7	MTT test for determination of RhE tissue viability after the exposure period	13
6.7.1	MTT incubation and Isopropanol extraction	13
6.7.2	Absorbance measurements	14
6.8	Test acceptance criteria	14
6.9	Data calculation steps	15
6.9.1	General	15
6.9.2	Isopropanol background control for OD in RhE assay	15
6.9.3	Negative DPBS or PBS treated controls	15
6.9.4	Positive control	15
6.9.5	Tested extract and VC samples (TTs)	15

6.10	Data interpretation — Prediction model	16
6.11	Method documentation sheet	16
6.12	Test report	16
<b>7</b>	<b><i>In vivo</i> irritation tests</b>	<b>17</b>
7.1	General	17
7.2	Animal irritation test by skin exposure	17
7.2.1	Principle	17
7.2.2	Test materials	18
7.2.3	Animals and husbandry	18
7.2.4	Test procedure	18
7.2.5	Observation of animals	20
7.2.6	Evaluation of results	20
7.2.7	Test report	21
7.3	Animal irritation test by intracutaneous (intradermal) administration	22
7.3.1	Introduction	22
7.3.2	Exclusion from test	22
7.3.3	Test sample	22
7.3.4	Animals and husbandry	22
7.3.5	Test procedure	23
7.3.6	Observation of animals	23
7.3.7	Evaluation of results	24
7.3.8	Test report	24
<b>8</b>	<b>Human skin irritation test</b>	<b>25</b>
8.1	Introduction	25
8.2	Initial considerations	25
<b>Annex A (normative) Preparation of materials for irritation testing</b>		<b>28</b>
<b>Annex B (informative) Test method check list for <i>in vitro</i> irritation testing using reconstructed human epidermis models</b>		<b>30</b>
<b>Annex C (informative) Example of method documentation sheet for reconstructed human epidermis models</b>		<b>30</b>
<b>Annex D (normative) Special irritation tests</b>		<b>37</b>
<b>Annex E (normative) Human skin irritation test</b>		<b>53</b>
<b>Annex F (informative) Background information on irritation tests</b>		<b>57</b>
<b>Bibliography</b>		<b>59</b>