

# ISO 7405:2025-06 (E)

## Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

### Contents

Page

Foreword.....v

Introduction.....vi

**1 Scope.....1**

**2 Normative references.....1**

**3 Terms and definitions.....2**

**4 Categorization of medical devices.....3**

4.1 Categorization by nature of contact.....3

4.1.1 General.....3

4.1.2 Non-contact devices.....3

4.1.3 Surface-contacting devices.....3

4.1.4 External communicating devices.....3

4.1.5 Implant devices used in dentistry.....3

4.2 Categorization by duration of contact.....4

4.2.1 General.....4

4.2.2 Limited exposure devices.....4

4.2.3 Prolonged exposure devices.....4

4.2.4 Long-term exposure devices.....4

**5 Biological evaluation process.....4**

5.1 General.....4

5.2 Selection of tests and overall assessment.....5

5.3 Selection of test methods.....5

5.4 Types of test.....5

5.4.1 General.....5

5.4.2 Physical and chemical characterization.....5

5.4.3 Group I.....5

5.4.4 Group II.....6

5.4.5 Group III.....6

5.5 Re-evaluation of biocompatibility.....6

**6 Test procedures specific to dental materials.....7**

6.1 Recommendations for sample preparation.....7

6.1.1 General.....7

6.1.2 General recommendations for sample preparation.....7

6.1.3 Specific recommendations for light curing materials.....7

6.1.4 Specific recommendations for chemically setting materials.....8

6.1.5 Positive control material.....8

6.2 Agar diffusion test.....8

6.2.1 Objective.....8

6.2.2 Cell line.....8

6.2.3 Culture medium, reagents and equipment.....8

6.2.4 Sample preparation.....9

6.2.5 Control materials.....9

6.2.6 Test procedure.....9

6.2.7 Parameters of assessment.....10

6.2.8 Assessment of results.....11

6.2.9 Test report.....11

6.3 Filter diffusion test.....11

6.3.1 Objective.....11

6.3.2 Cell line.....11

|  |   |           |
|--|---|-----------|
| 6.3.3  | Culture medium, reagents and equipment..... | 12        |
| 6.3.4  | Sample preparation .....                    | 12        |
| 6.3.5  | Control materials .....                     | 12        |
| 6.3.6  | Test procedure.....                         | 12        |
| 6.3.7  | Assessment of cell damage.....              | 13        |
| 6.3.8  | Assessment of results .....                 | 13        |
| 6.3.9  | Test report.....                            | 14        |
| 6.4  | Pulp and dentine usage test.....            | 14        |
| 6.4.1  | Objective .....                             | 14        |
| 6.4.2  | Animals and animal welfare.....             | 14        |
| 6.4.3  | Test procedure.....                         | 14        |
| 6.4.4  | Assessment of results .....                 | 20        |
| 6.4.5  | Test report.....                            | 20        |
| 6.5  | Pulp capping test.....                      | 20        |
| 6.5.1  | Objective .....                             | 20        |
| 6.5.2  | Animals and animal welfare.....             | 20        |
| 6.5.3  | Test procedure.....                         | 20        |
| 6.5.4  | Assessment of results .....                 | 22        |
| 6.5.5  | Test report.....                            | 22        |
| 6.6  | Endodontic usage test.....                  | 22        |
| 6.6.1  | Objective .....                             | 22        |
| 6.6.2  | Animals and animal welfare.....             | 23        |
| 6.6.3  | Test procedure.....                         | 23        |
| 6.6.4  | Assessment of results .....                 | 25        |
| 6.6.5  | Test report.....                            | 25        |
| <b>Annex A (informative) Types of test to be considered for evaluation of biocompatibility of medical devices used in dentistry.....</b> |   | <b>26</b> |
| <b>Annex B (informative) Dentine barrier cytotoxicity test.....</b>  |   | <b>28</b> |
| <b>Annex C (informative) Endosseous dental implant usage test.....</b>   |   | <b>35</b> |
| <b>Annex D (informative) Antioxidant responsive element (ARE) reporter assay oxidative stress test.....</b>                              |   | <b>39</b> |
| <b>Annex E (informative) Margin of safety (MoS) for medical devices used in dentistry.....</b>   |   | <b>48</b> |
| <b>Bibliography.....</b>   |   | <b>57</b> |