

DIN EN ISO 16408:2025-09 (E)

Dentistry - Oral care products - Oral rinses (ISO 16408:2025)

| Contents | | Page |
|-----------------|---------------------------------------------------------------------------------------|-------------|
| | Foreword | iv |
| | Introduction | vi |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | Classification | 2 |
| 5 | Requirements | 2 |
| 5.1 | pH value..... | 2 |
| 5.2 | Total fluoride concentration and maximum amount of fluoride..... | 2 |
| 5.3 | Unintended heavy metal..... | 2 |
| 5.4 | Compatibility with oral tissues..... | 2 |
| 5.5 | Microbial contamination..... | 2 |
| 5.6 | Stability against ageing..... | 3 |
| 5.7 | Container and dispensing system..... | 3 |
| 5.8 | Readily fermentable carbohydrates..... | 3 |
| 6 | Sampling | 3 |
| 7 | Test methods | 3 |
| 7.1 | General..... | 3 |
| 7.2 | Visual inspection..... | 3 |
| 7.3 | Determination of pH value..... | 3 |
| 7.4 | Determination of total fluoride concentration and mass of ionic fluoride..... | 3 |
| 7.4.1 | General..... | 3 |
| 7.4.2 | Reagents..... | 4 |
| 7.4.3 | Apparatus..... | 4 |
| 7.4.4 | Preparation of sample solution..... | 4 |
| 7.4.5 | Sample analysis..... | 4 |
| 7.4.6 | Expression of results..... | 4 |
| 7.5 | Determination of stability against ageing..... | 5 |
| 7.6 | Pass/fail criteria..... | 5 |
| 8 | Test report | 5 |
| 9 | Accompanying information | 6 |
| 9.1 | Manufacturer's instructions for use..... | 6 |
| 9.2 | Information on the primary container and on the secondary container if it exists..... | 6 |
| 10 | Packaging | 6 |
| | Bibliography | 7 |