

DIN EN ISO 16408:2015-12 (E)

Dentistry - Oral care products - Oral rinses (ISO 16408:2015)

Contents		Page
Foreword		3
Introduction		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	5
4	Classification	6
5	Requirements	6
5.1	pH value	6
5.2	Total fluoride concentration and maximum amount of fluoride	6
5.3	Unintended heavy metals	6
5.4	Compatibility with oral tissues	6
5.5	Microbial contamination	7
5.6	Stability against ageing	7
5.7	Container and/or dispensing system	7
5.8	Readily fermentable carbohydrates	7
6	Sampling	7
7	Test methods	7
7.1	General	7
7.2	Visual inspection	7
7.3	Determination of pH value	7
7.4	Determination of stability against ageing	7
7.4.1	Test	7
7.4.2	Compliance	8
7.5	Pass/fail criteria	8
8	Test report	8
9	Accompanying information	8
9.1	Manufacturer's instructions for use	8
9.2	Information on the primary container, and on the secondary container, if it exists	8
10	Packaging	9
Annex A (normative) Determination of fluoride in oral rinses containing ionic fluoride compounds .		10
Bibliography		13