DIN EN ISO 20749:2018-11 (E)

Dentistry - Pre-capsulated dental amalgam (ISO 20749:2017)

Contents

Page

European foreword ... **4**

Foreword ... **5**

Introduction ... **6**

1 Scope ... **7**

2 Normative references ... **7**

3 Terms and definitions ... **8**

4 Requirements ... **9**
4.1 Package and capsule contamination ... 9
4.2 Chemical composition and purity of the dental amalgam alloy ... 9
4.3 Large particles in the dental amalgam alloy powder ... 9
4.4 Loss of mass from the capsule during mixing ... 9
4.5 The yield of amalgam from the capsule ... 9
4.6 Consistency of the dental amalgam from capsule to capsule ... 10
4.7 Properties of the dental amalgam ... 10
4.7.1 Creep ... 10
4.7.2 Dimensional changes during hardening ... 10
4.7.3 Compressive strength at 1 h ... 10
4.7.4 Compressive strength at 24 h ... 10
4.8 Appearance of the mixed dental amalgam before setting ... 10
4.9 Length tolerance for the capsule ... 10

5 Sampling ... **11**

6 Test methods ... **11**
6.1 Package and capsule contamination ... 11
6.1.1 Principle ... 11
6.1.2 Test sample ... 11
6.1.3 Apparatus ... 11
6.1.4 Procedure ... 11
6.1.5 Expression of the results ... 11
6.1.6 Report ... 11
6.2 Chemical composition and purity of the dental amalgam alloy ... 11
6.2.1 Principle ... 11
6.2.2 Test sample ... 12
6.2.3 Apparatus ... 12
6.2.4 Procedure ... 12
6.2.5 Expression of results ... 12
6.2.6 Report ... 12
6.3 Large particles in the dental amalgam alloy powder ... 12
6.3.1 Principle ... 12
6.3.2 Test sample ... 13
6.3.3 Apparatus ... 13
6.3.4 Test procedure ... 13
6.3.5 Expression of the results ... 13
6.3.6 Report ... 13
6.4 Loss of mass from the capsule during mixing ... 14
6.4.1 Principle ... 14
6.4.2 Test sample ... 14
6.4.3 Apparatus ... 14
6.4.4 Test procedure ... 14
6.4.5 Expression of the results ... 15
6.4.6 Report ... 15

6.5 Yield of amalgam from the capsule ... 15
6.5.1 Principle ... 15
6.5.2 Test sample ... 15
6.5.3 Apparatus ... 15
6.5.4 Test procedure ... 16
6.5.5 Expression of the results ... 16
6.5.6 Report ... 16
6.6 Consistency of the dental amalgam from capsule to capsule ... 16
6.6.1 Principle ... 16
6.6.2 Test sample ... 17
6.6.3 Apparatus ... 17
6.6.4 Test-piece production ... 18
6.6.5 Microhardness measurement ... 19
6.6.6 Expression of the results ... 19
6.6.7 Report ... 20
6.7 Properties of the dental amalgam ... 20
6.7.1 Principle ... 20
6.7.2 Sample ... 20
6.7.3 Mould for the preparation of cylindrical test-pieces for determining creep, dimensional change during hardening and compressive strength ... 20
6.7.4 Preparation of cylindrical test-pieces to determine compliance with the requirements for creep, dimensional change during hardening and compressive strength ... 24
6.7.5 Determination of creep ... 26
6.7.6 Determination of dimensional change during hardening ... 27
6.7.7 Determination of compressive strength ... 28
6.8 Appearance of the mixed dental amalgam before setting ... 29
6.8.1 Principle ... 29
6.8.2 Apparatus ... 30
6.8.3 Test procedure ... 30
6.8.4 Expression of the results ... 30
6.8.5 Report ... 31
6.9 Length tolerance for the capsule ... 31
6.9.1 Principle ... 31
6.9.2 Test sample ... 31
6.9.3 Apparatus ... 31
6.9.4 Test procedure ... 31
6.9.5 Expression of the results ... 31
6.9.6 Report ... 31

7 Marking, labelling and packaging ... 32
7.1 Packaging ... 32
7.2 Marking and labelling ... 32
7.2.1 Information ... 32
7.2.2 Labelling of a package for dental mercury ... 32
7.2.3 Labelling of the outer surface of package or container used for shipping ... 33
7.3 Manufacturer's instructions ... 33
7.3.1 General instructions ... 33
7.3.2 Precautionary notes ... 33

Bibliography ... 34