Revised ANSI/ADA Standard No. 25/ISO 6873 Approved by ANSI: December 17, 2015



Revised American National Standard/ American Dental Association

Standard No. 25

Dental Gypsum Products

Identical adoption of ISO 6873:2013, Dentistry — Gypsum products.

ADA American
Dental
Association®
Council on
Scientific Affairs



ASSOCIATION STANDARD NO. 25 FOR DENTAL GYPSUM PRODUCTS

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 25 for Dental Gypsum Products. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of revised ADA Standard No. 25 as an American National Standard on December 17, 2015.

The ADA Standards Committee on Dental Products thanks the members of Working Group 2.18 on Investments and the organizations with which they were affiliated at the time the standard was developed:

William Dunn (chairman), U.S. Air Force, Helotes, TX; Shannon Mills, Northeast Delta Dental, Concord, NH; James Ragain, University of Tennessee, Memphis, TN; Sharon Stanford, American Dental Association, Chicago, IL; and Jeff Zawada, A-Dec, Inc., Newberg, OR.

STANDARD NO. 25 FOR DENTAL GYPSUM PRODUCTS

Foreword

(This Foreword does not form a part of the Proposed Revision of ANSI/ADA Standard No. 25 for Dental Gypsum Products).

This revised standard is an identical adoption of ISO 6873:2013, Dentistry-Gypsum products. ADA SCDP Working Group 2.18 on Investments reviewed the international standard and found it acceptable for adoption as revised ANSI/ADA Standard No. 25. This standard cancels and replaces ANSI/ADA Standard No. 25:2000 (R2010).

STANDARD NO. 25 FOR DENTAL GYPSUM PRODUCTS

Introduction

This revision was necessary because gypsum products have been marketed since the last editions of ANSI/ADA Standard No. 25 and ISO 6873 were published, which have properties (required for newly introduced dental technology) for which the requirements set in that edition were not appropriate. In this edition the classification has been altered to take this into account and, in so doing, requirements have been set appropriately. In addition there was concern that Type 4 dental stone used for CAD/CAM models should not produce significant setting expansion at times beyond the 2 h period at which setting expansion was measured; therefore a requirement has been set. For this edition, the setting expansion for Type 4 dental stone is measured at 24 h as well.

STANDARD NO. 25 FOR DENTAL GYPSUM PRODUCTS

1 Scope

This standard gives a classification of, and specifies requirements for, gypsum products used for dental purposes such as making oral impressions, molds, casts, dies or model bases, and mounting models. It specifies the test methods to be employed to determine compliance with these requirements. It also includes requirements for the labelling of packaging and for adequate instructions to accompany each package.

This standard does not apply to dental bone graft substitutes composed of calcium sulfate hemihydrate (or gypsum).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1302, Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation

ISO 1942, Dentistry — Vocabulary

ISO 3696:1987, Water for analytical laboratory use — Specification and test methods

ISO 8601, Data elements and interchange formats — Information interchange — Representation of dates and times

ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

gypsum product

dental product composed essentially of a hemihydrate of calcium sulfate and any necessary modifiers

NOTE Coloring matter and flavoring, if present, are regarded as necessary modifiers.

4 Classification

The five types of gypsum product used in dentistry are classified in accordance with this International Standard as follows:

- a) **Type 1:** Dental plaster for impressions;
- b) **Type 2:** Dental plaster for mounting (Class 1) and for models (Class 2);
- c) **Type 3:** Dental stone for models;