



Therapeutic Goods Order No. 67 - Standard for Dental Materials

as amended

made under section 10 of the

Therapeutic Goods Act 1989

This compilation was prepared on 9 May 2007
taking into account amendments up to *Therapeutic Goods Order No. 67A -
Amendment to Therapeutic Goods Order No. 67 - Standard for Dental Materials*

Prepared by the Office of Legislative Drafting and Publishing,
Attorney-General's Department, Canberra

Therapeutic Goods Order No. 67

Standard for Dental Materials

I, TERRY SLATER, delegate of the Minister of State for Health and Aged Care for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with section 10 of the said Act, HEREBY:

(1) **REVOKE** Therapeutic Goods Order No. 57 “Dental Materials”, signed by the delegate on 7 April 1997 and gazetted on 23 April 1997; and

(2) **DETERMINE THAT:**

(a) the matters specified in each of the International Standards made and published by the International Organisation for Standardisation, listed in Column 1 of the Schedule to this Order, constitute a standard for the therapeutic goods, or class of therapeutic goods, described in Column 2 of the Schedule in relation to that International Standard; and

(b) the International Standards ISO 9917:1991(E) Dental water-based cements and ISO 9917-2:1998(E) Dental water-based cements – Part 2: Light-activated cements shall both constitute the standard for water-based dental cements, subject to the following modification:

(i) Subclause 8.2 (**Marking**) of *ISO 9917:1991 (E) Dental water-based cements*, shall be omitted and replaced with the following new subclause 8.2:

“8.2 Marking

The requirements of *Therapeutic Goods Order No. 37 General Requirements for Labels for Therapeutic Devices* shall apply.” ; and

(ii) Subclause 8.2 (**Marking**) of *ISO 9917-2 1998(e) Dental water-based cements – Part 2: Light-activated cements*, shall be omitted and replaced with the following new subclause 8.2:

“8.2 Marking

The requirements of *Therapeutic Goods Order No 37 General Requirements for Labels for Therapeutic Devices* shall apply.”

This Order commences on the date this Order is gazetted in the *Commonwealth Gazette*.

Schedule Dental Materials

Column 1 Standard	Column 2 Goods
ISO 1559-1995 (E) “Dental materials - Alloys for dental amalgam” Third edition	Alloys for dental amalgam
ISO 1560 – 1985 (E) “Dental mercury” Second edition	Dental mercury
ISO 6876 – 1986 (E) “Dental root canal sealing Materials” Second edition	Dental root canal sealing materials
ISO 3107: 1988 (E) “Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements” Second edition	Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements
ISO 6874: 1988 (E) “Dental resin-based pit and fissure sealants” First edition	Dental resin-based pit and fissure sealants
ISO Standard 4049: 2000 Dentistry – Polymer-based filling, restoration and luting materials, Third edition	Polymer-based filling, restoration and luting materials

Table of Instruments

Notes to the *Therapeutic Goods Order No. 67 - Standard for Dental Materials*

Note 1

The Therapeutic Goods Order No. 67 - Standard for Dental Materials in force under section 10 of the *Therapeutic Goods Act 1989* as shown in this compilation is amended as indicated in the Tables below.

Table of Instruments

Title	Date of notification in Gazette	Date of commencement	Application, saving or transitional provisions
<i>Therapeutic Goods Order No. 67 – Standard for Dental Materials</i> (F2007B00467)	14 Mar 2001 (see Gazette 2001, No. GN10)	14 Mar 2001	
<i>Therapeutic Goods Order No. 67A – Amendment to Therapeutic Goods Order No. 67 – Standard for Dental Materials</i> (F2007B00466)	14 Aug 2002 (see Gazette 2002, No. GN32)	14 Aug 2003	—

Table of Amendments

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Schedule	
Schedule.....	am. Order No. 67A
