

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

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 subsection 10(4) 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*.

Dated this 23rd day of February 2001

TERRY SLATER
Delegate of the Minister for Health and Aged Care

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 4049: 1988 (E) “Dentistry – resin-based filling materials” Second edition including Technical Corrigendum 1:1992	Dental resin-based filling materials