

IMPORTANT NOTICE

to all Dental Professionals

Recently the **Australian Therapeutic Goods Administration** (TGA) made significant regulatory changes that concern the majority of clinical products used by Dental Professionals.

The **Australian Register of Therapeutic Goods** (ARTG) is a computer database of approved therapeutic goods. Therapeutic goods are divided broadly into two classes - medicines and medical devices. Unless exempt, therapeutic goods must be approved before they may be supplied and used in Australia. It is now your legal obligation to make sure that patients always are treated in complete safety using TGA approved therapeutic goods. Detailed information can be downloaded from www.tgasime.health.gov.au



How do you make sure that your dental surgery is being supplied with TGA scrutinized and approved Medical Devices?

Simply make copies of this sample REQUEST below and send a filled in copy to your suppliers for each new clinical device ordered!

The returned copy CERTIFICATE will be your assurance of legal compliance and optimal safety.

Additionally this will aid and support your dental suppliers that do adhere to current regulations and legal obligations by creating a "level playing field" in the market.

Example of a valid ARTG CERTIFICATE:

 TGA <small>Therapeutic Goods Administration</small> PO Box 100, Woden, ACT 2606, Australia Telephone: (02)6232 8444. Fax: (02)6232 8241 ABN 40 939 406 804		 <small>Commonwealth Department of</small> Health and Ageing
<u>CERTIFICATE FOR INCLUSION OF A MEDICAL DEVICE</u>		
ARTG Number	146060	
ARTG Labelname	Norlin Dental - Bur, dental, diamond	
Sponsor	Norlin Dental	
Commencement Date	16/10/2007	
Manufacturer	North Bel International SRL Italy	
Device Class	Class IIa	
GMDN Code	16670 Bur, dental, diamond	
ARTG Product Number and Name	234174 Bur, dental, diamond	



REQUEST FOR ARTG CERTIFICATE COPY

Dear Madam/Sir,

Before ordering further dental supplies from your company, I must be provided with a copy of relevant **CERTIFICATE FOR INCLUSION OF A MEDICAL DEVICE**. Please mail / fax a copy of the original ARTG document with information of ARTG Number, ARTG Label name, Sponsor, Commencement Date, Manufacturer, Device Class, GMDN Code and ARTG Product Number and Product Name, thank you.

Australian Supplier.....

Product Concerned.....

Product Description and Price.....

Catalogue Number or Code #.....

- **Reply to** (contact person).....
- **Reply facsimile** (area)..... (number).....