

February 29, 2008

Dear Ivoclar Vivadent Customer:

RE: Lead Found in Dental Prosthesis Made in China

You may have heard that an Ohio dental patient, after experiencing an adverse reaction, reported that her porcelain bridge made in China was contaminated with lead. This story was then covered by a TV Station in Columbus, Ohio. You can view this broadcast at www.10tv.com. The purpose of this letter is to inform you that all of Ivoclar Vivadent's products, including our ceramics and alloys, are safe and effective and meet all regulatory requirements.

For more than 80 years, Ivoclar Vivadent has been committed to developing the highest quality dental material systems. We are ISO 13485 certified for medical devices and all of our products are registered with the FDA and Health Canada. Our quality system worldwide undergoes a strict annual audit by third party registered Notified Bodies. All of our alloy and ceramic products comply with ADA and International product standards prior to sale. Our alloy and ceramic products undergo biocompatibility testing including cytotoxicity, radioactivity and solubility testing prior to sale. We voluntarily participate in the Identalloy and IdentCERAM programs conforming to ADA-sanctioned guidelines for alloy and zirconia compositions. A listing of all standards followed by Ivoclar Vivadent is attached to this letter.

In reference to recent questions concerning lead in dental prosthesis, we believe the "Solubility Test" conducted in accordance with ISO 6872 is the standard for testing safety of dental prosthesis in the mouth. **In standardized solubility tests in accordance with ISO 6872, there is no detectable level of lead from any Ivoclar Vivadent alloy or ceramic.**

Based on our own quality controls and the validation of outside agencies including the FDA and Health Canada, we are confident that all of our products are safe. With the industry's largest dental research and development facility and over 30 education centers worldwide, Ivoclar Vivadent is committed to providing superior quality dental products and world-class customer support. Thank you for your business and please feel free to contact us if you have any questions.

Sincerely,

IVOCLAR VIVADENT, INC.

A handwritten signature in black ink, appearing to read "Robert A. Ganley".

Robert A. Ganley
President & CEO

NATIONAL AND INTERNATIONAL STANDARDS FOLLOWED BY IVOCCLAR VIVADENT

Number	Title	Current Revision Year
Quality System Standards		
ISO 13485	Medical Devices – Quality Management Systems - Requirements for regulatory purposes.	2003
Labeling Standards		
EN 980	Graphical symbols for use in the labeling of medical devices	2003
DIN EN 1041	Information supplied by the manufacturer with medical devices	1998
ISO 15223 +A1 + A2	Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied	2000 2002 2004
European Regulations and Guidelines		
MEDDEV 2.12-1 rev. 4	Guidelines on Medical Devices Vigilance System	April 2001
93/42/EEC	Council Directive concerning Medical Devices (MDD)	June 14 1993
MEDDEV 2.7.1	Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies	April 2003
Canadian Regulations		
Schedule 1101	Canadian Medical Device Regulations	1998 Amend. 2002
GD003/ Rev DR-MDB	Draft Guidance Document – Guidance for Medical Devices Complaint Handling and Recalls	September, 1998
GD005/Rev DR-MDB	Draft Guidance Document – Mandatory and Voluntary Problem Reporting for Medical Devices	July, 2001
FDA Regulations		
21 CFR Parts 800 to 1299	Food and Drug Administration Regulations. Subchapter H – Medical Devices	Rev. as of 4/1/07
21 CFR Part 7	Guidance to Manufacturers with respect to Voluntary removal or correction	2001
Risk Assessment/Management		
ISO 14971	Medical Devices – Application of Risk Management to medical devices	2007
Product Standards		
ISO 1560	Dental Mercury	1985
ISO 1561	Dental Casting Wax	1995
ISO 1563	Dental Alginate impression material	1990
ISO 1567/ Am. 1	Dentistry – Denture Base Polymers	2000 2003
ISO 4049	Dentistry – Polymer-based filling, restorative and luting materials	2000
ISO 4823	Elastomeric Impression Materials	2004
ISO 6872	Dental Ceramic	1995 & A1:1997
ISO 6874	Dental resin-based pit and fissure sealants	2005
ISO 9693	Metal-ceramic dental restorative systems.	1999
ISO 9333	Brazing materials.	2006
ISO 9694	Dental Phosphate bonded Casting Investments	1996
ISO 9917	Water based cements	2003
ISO 10271	Dental metallic materials – Corrosion test methods	2001
ISO 10477	Polymer Based crown & Bridge Material	2004
ISO 11137-1	Sterilization of Health Care Products – Radiation Part 1. Requirements for development, validation and routine control of a sterilization process for medical devices	
ISO/TR 14696	Medical Devices – Quality Management System – Guidance on the Application of ISO 13485:2003	2004
ISO 17664	Sterilization of medical devices: Information to be provided by the manufacturer for the processing of resterilizable medical devices	2004

ISO 22112	Dentistry – Artificial Teeth for dental Prostheses	2005
ISO 22674	Dentistry – Metallic Material for fixed and removable restorations and appliances	2006
ISO 24234	Dentistry: Mercury and alloys for dental amalgam	2004
IEC 60601-1	Medical Electrical Equipment. Part 1: General requirements for safety	2005

IEC 60601-1-4	Medical Electrical Equipment – General Requirements for safety – Collateral Standard: Programmable electrical medical systems.	2000
IEC 60601-2-22	Medical Electrical Equipment, Part 2 Particular requirements for the safety of diagnostic and therapeutic laser equipment	1995
IEC-60825-1:	Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide	2007
ANSI Z136.1	American National Standard for Safe Use of Lasers	2000
ANSI Z136.3	American National Standard for Safe Use of Lasers in Health Care Facilities	2005
CSA Z386-01	Laser Safety in Health Care Facilities	2001
General Application in Dentistry		
EN 1641	Dentistry – Medical Devices for dentistry – Materials	2004
Biological Evaluation of Medical Devices		
ISO 10993-1/Am. 1	Evaluation and Testing	2003 2006
ISO 10993-3	Tests for genotoxicity	2003
ISO 10993-5	Tests for cytotoxicity	1999
ISO 10993-10	Tests for irritation	2002

ADA Specifications		
ANSI/ADA Spec. No. 1	Alloy for Dental Amalgam & 1a, Addendum	2003
ANSI/ADA Spec. No. 2	Gypsum Bonded Casting Investment for Dental Gold Alloy	March 2002
ANSI/ADA Spec. No. 4	Dental Inlay Casting Wax	2003
ANSI/ADA Spec. No. 5	Dental Casting Alloys	October 1997
ANSI/ADA Spec. No. 6	Dental Mercury	February 1987
ANSI/ADA Spec. No. 12	Denture Base Resins	September 2002
ANSI/ADA Spec. No. 13	Denture ColdCuring Repair Resin	April 1999
ANSI/ADA Spec. No. 14	Dental Base Metal Casting Alloys	1998
ANSI/ADA Spec. No. 15	Synthetic Polymer Teeth	March 2000
ANSI/ADA Spec. No. 17	Denture Base Temporary Relining Resin	April 1999
ANSI/ADA Spec. No. 18	Dental Alginate Impression Material	June 1992
ANSI/ADA Spec. No. 19	Elastomeric Dental Impression Material	1993
ANSI/ADA Spec. No. 22	Intraoral Dental Radiographic Film	December 1969
ANSI/ADA Spec. No. 23	Dental Excavating Burs	April 1999
ANSI/ADA Spec. No. 24	Dental Baseplate Wax	2003
ANSI/ADA Spec. No. 25	Dental Gypsum Products	March 2000
ANSI/ADA Spec. No. 27	Direct Filling Resins	1997
ANSI/ADA Spec. No. 30	Zinc Oxide Eugenol and NonEugenol Cements	September 2000
ANSI/ADA Spec. No. 33	Dental Terminology & 33a Supplement	2003
ANSI/ADA Spec. No. 37	Dental Abrasive Powders	May 2001
ANSI/ADA Spec. No. 38	Metal Ceramic Systems	March 2000
ANSI/ADA Spec. No. 39	Pit and Fissure Sealants	1999
ANSI/ADA Doc. No. 41 & 41a, Addendum	Recommended Standard Practices for Biological Evaluation of Dental Materials	January 2001
ANSI/ADA Spec. No. 42	Phosphate Bonded Investments	March 2002
ANSI/ADA Spec. No. 43	Electrically Powered Dental Amalgamators	1995
ANSI/ADA Spec. No. 46	Dental Chairs	2003
ANSI/ADA Spec. No. 47	Dental Units	2003
ANSI/ADA Spec. No. 48	Ultraviolet Activator and Disclosing Lights	1989
ANSI/ADA Spec. No. 53	Polymer-Based Crown and Bridge Resins	March 1999

ANSI/ADA Spec. No. 57	Endodontic Sealing Materials	March 2000
ANSI/ADA Spec. No. 58	Root Canal Files, Type H (Hedstrom)	April 1997
ANSI/ADA Spec. No. 59	Portable Steam Autoclave Sterilizers	October 1992
ANSI/ADA Spec. No. 69	Dental Ceramic	December 1999
ANSI/ADA Spec. No. 75	Resilient Denture Liners	2003
ANSI/ADA Spec. No. 80	Color Stability Test Procedure	May 2001
ANSI/ADA Spec. No. 82	Combined Reversible/Irreversible Hydrocolloid Impression Materials	2003
ANSI/ADA Spec. No. 87	Impression Trays	February 1995
ANSI/ADA Spec. No. 88	Dental Brazing Alloys	March 2000
ANSI/ADA Spec. No. 93	Soldering Investments	March 2000
ANSI/ADA Spec. No. 96	Dental Water-Based Cements	September 2000
ANSI/ADA Spec. No. 97	Tarnish and Corrosion Testing	March 2002