

Leuven, March 15<sup>th</sup>, 2013<sup>1</sup>

Dear GC Europe customer,

You may have recently been informed about concerns in our industry regarding the use of Bis-GMA and Bisphenol A (BPA)<sup>2</sup> in relation to dental materials. As a company dedicated to its customers and products users, we would like to provide some clarification:

1. **NONE of GC dental products sold within Europe and all other territories under the operational responsibility of GC Europe contain Bisphenol A as an ingredient.**
2. A well-defined number of GC products contains Bisphenol A glycidylmethacrylate (also called Bis-GMA), which is not the same as Bisphenol A, namely GC Fiber Post, everX Posterior, StickRESIN and the everStick product line<sup>3</sup>. **All other products are free from this ingredient.** Studies have shown that Bis-GMA does not degrade into BPA intra-orally.<sup>4</sup>
3. A well-defined number of GC products contains Bis-MEPP, which is not the same as Bisphenol A; namely Kalore, G-ænial Posterior (**not** in G-ænial Anterior), G-ænial Flo, G-ænial Universal Flo and FujiCEM 2. All other products are free from this ingredient. **Bis-MEPP is not considered dangerous<sup>5</sup>.**

GC Europe is committed to providing clinically proven, quality dental products. Therefore you can reassure your customers and patients that GC Europe only sells products which are safe for dental use, according to national and international regulations and standards. These include continuous compliance with the European Union Medical Device Directive (MDD 93/42/EEC) and ISO 13845.

For further information on this subject, please do not hesitate to contact your local GC representative.

Sincerely,

  
Gideon Blumental  
Head Regulatory Affairs

  
Bart Dopheide  
Head Product Management

<sup>1</sup> The content of this statement is applicable under the current situation on signature date. GC Europe can not be held liable for any future changes that may occur.

<sup>2</sup> European Commission, European Union Risk Assessment Report, 4,4'-isopropylidenediphenol (bisphenol-A) (complete risk assessment in one document), 2010; Association Européenne des Spécialités Pharmaceutiques Grand Public, "Safety of Bisphenol A (BPA) in medical devices", 2010

<sup>3</sup> The everStick product line consists of everStick C&B, everStick NET, everStick ORTHO, everStick PERIO and everStick POST (0.9; 1.2; 1.5).

<sup>4</sup> A. Fleish, ed., "Bisphenol A and related compounds of dental materials", *Pediatrics*, 2010, nr 126, p 760-768

<sup>5</sup> Vibeke B. Michelsen, ed., "Detection and quantification of monomers in unstimulated whole saliva after treatment with resin-based composite fillings in vivo", *Eur. J. Oral Sci.*, 2012, nr 120, p 94