

Leuven, July 15th, 2016¹

Dear GC Europe customer,

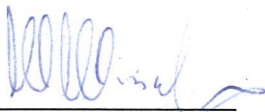
You may have been informed about concerns in our industry regarding the use of Bis-GMA and Bisphenol A (BPA)² in relation to dental materials. As a company dedicated to its customers and products users, we would like to provide some clarification:

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) and/or Ethoxylated Bisphenol A dimetacrylate (also called Bis-EMA). These substances are not the same as Bisphenol A. GC products containing one or both of these substances are listed in Annex. **All other GC products are free from these ingredients.**
3. Neither Bis-GMA nor Bis-EMA can be converted into BPA in saliva and a comprehensive scientific literature review concludes that Dental materials containing Bis-GMA or Bis-EMA pose no human health risks.³ This conclusion is consistent with the opinion adopted by the EC Scientific Committee on Emerging and Newly Identified Health Risks stating that oral exposure to BPA via dental material poses a negligible risk to human health and is far below the exposure to BPA via food⁴.

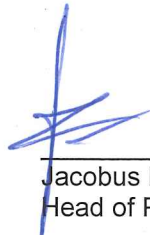
GC Europe is committed to providing clinically proven, quality dental products. Therefore you can reassure your customers and patients that GC Europe only sells products which are safe for dental use, according to national and international regulations and standards. These include continuous compliance with the European Union Medical Device Legislations (present MDD 93/42/EEC and future MDR) and ISO 13485.

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

Sincerely,



Mario Minale
Head of Regulatory Affairs



Jacobus Dopheide
Head of Product Management

¹ The content of this statement is applicable under the current situation on signature date. GC Europe cannot be liable for any future changes that may occur.

² 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

³ Chen L., Suh BI, "Bisphenol A in Dental Materials: A Review.", *JSM Dent 1*, 2013: 1004., p 4

⁴ Opinion on The safety of the use of bisphenol A in medical devices adopted by written procedure on 18 February 2015 by the Scientific Committee on Emerging and Newly Identified Health Risks. p 16, §4 and p 118, §4



List of GC products containing: Bisphenol A glycidylmethacrylate (Bis-GMA) and/or Ethoxylated Bisphenol A dimetacrylate (Bis-EMA).

	Bis-GMA	Bis-EMA
Ceramic Primer II	Present	-
everStick product lineⁱ	Present	-
everX Posterior	Present	-
Fiber Post	Present	-
G-Multi Primer	Present	-
StickRESIN	Present	-
Essentia Light Enamel, Dark Enamel and Opalescent Modifier	Present	Present
G-CEM LinkForce	Present	Present
Essentia Masking Liner	-	Present
FujiCEM 2	-	Present
G-ænial Posterior (not in G-ænial Anterior)	-	Present
G-ænial Flo & Flo-X	-	Present
G-ænial Universal Flo	-	Present
Kalore	-	Present

ⁱ The everStick product line consists of everStick C&B, everStick NET, everStick ORTHO, everStick PERIO and everStick POST (0.9; 1.2; 1.5).