

Friday, 23 March 2007

**IMPORTANT NOTE ON PRODUCTION STANDARDS AT CAPITOL EUROPE S.A.**

**Certificate for Food grade Products: Dairy and General Sampling Vials**

Hereby we certify that the raw materials used in the composition of the Dairy and General Sampling Vials are according to the European Regulation for products and goods in contact with food.

More precisely, we do certify that our vials are in conformity with Regulation 89/109/CEE.

Upon request we will address to the user a copy of the food certificate of raw materials used to produce our vials.

Nevertheless, it is recommended to the user of our vials to verify and test that the products packaged in the vial are in conformity with the current regulation.

This certificate will become obsolete at any regulation change. At due date, the user will have to claim the renewal of this certificate.

**Sterility certificates**

Due to our patented process in manufacturing we can guarantee the sterility of our products – which is frequently and randomly tested by an independent laboratory.

Our injection moulding process is patented: we close the vials into the mould before it is ejected and transferred to the transport box.

We manufacture in clean rooms class 100000 and we close the one-piece hinged vials into the mould while they are still hot. This allows to guarantee that there is absolutely no pollution into the vials (no manual handling and no exposure open) and moreover this allows to achieve a perfectly tight seal after the cooling.

We offer a totally aseptic process and guarantee that there is no live bacteria into the vials because the polypropylene is injected at temperatures higher than 200 °C.

Upon request we can provide a sterility validation report in conformity with the European Pharmacopeia - 4<sup>th</sup> Edition 2.6.1. - and the technical annex relative to the N°1-1021 (ICARE laboratory reports).

This information does not dispense the customer to follow the specific rules which may be specific to his use.

**Certificate for absence of « heavy metal particles »**

We hereby certify that all our products are free of heavy metal particles.

All our products comply with the following regulation:

- European Directive 94/62 CE from December 20, 1994, relative to packaging and waste material.

In addition you will please note that the European Directive 67/548 CE from June 27, 1960, relative to the classification, the packaging and the labelling of dangerous and hazardous products is not concerning our products and therefore not applicable.

Don't hesitate if you need to know any more specific information,

With kind regards

**Yves DOLLE**  
Quality Manager