



# Statement of Quality

#### Our Commitment to customers:

Viaflo consumables are produced from virgin medical grade materials using precise and consistent manufacturing techniques that insure quality and excellent performance. We strive to exceed our customers' expectations and encourage continuous feedback.

Our product lots are traceable down to the corresponding raw materials used and date produced. Our manufacturing process incorporates consistent in-line inspection throughout all phases of fabrication and assembly. All consumables are produced in a clean-room setting to insure purity and cleanliness. Viaflo consumables produced under these strict conditions are contaminant free and consistent from lot-to-lot.

## Sterility:

Dose validation is consistent with EN 552, AMO/ISO 11137:2006 standards which are used to establish the dose required for sterilization based on the bio-burden level for each product for its specific qualities and packaging. These products are manufactured, packaged and sterilized under controlled conditions and are considered sterile until opened. Validation and dosage level is then monitored at regular intervals. Sterile products have been Gamma irradiated within the minimum and maximum dosage range specified for Viaflo sterile products:

Minimum Specified Dose (kGy) 12.5 Maximum Specified Dose (kGy) 22.5

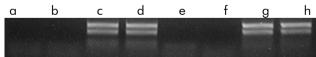
## Pyrogen Testing:

ViaPure products have been tested for Endotoxins. The Limulus Ameobacyte Lysate (LAL) test procedure is used according to USP 31 (United States Pharmacopeia) guidelines using the LAL gel clot procedure by technicians certified according to USP/FDA guidelines for medical devices. Endotoxin acceptance level is < 0.06EU/mL.

### **PCR** Inhibitors:

Approved lots are free of detectable human and mouse genomic DNA contamination, and will not inhibit PCR reactions.

 $\sqrt{\mbox{ PCR Certified}}$   $\sqrt{\mbox{ No PCR inhibition}}$   $\sqrt{\mbox{ Free of detectable Human DNA}}$   $\sqrt{\mbox{ Free of detectable Mouse DNA}}$  Gell Photos:

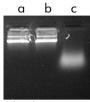


Lane (a) negative control, lane (b) negative control, lane (c) positive control 30 pg each DNA, lane (d) positive control 30 pg each DNA, lane (e) DNA contamination test of the products listed above, lane (f) DNA contamination test of the submitted products, lane (g) product PCR inhibition test, lane (h) product PCR inhibition test.

## Ribonuclease (RNase):

ViaPure lots are tested for RNase activity by the following protocol:

Products were extracted in RNase free water. The extract was then added to an RNA standard. The RNA standard was incubated at 37°C for 1 hour and then heated to 65°C for 5 minutes. RNA samples were then run on an agarose gel, photographed and evaluated for degradation. No visible degradation was found present in the product samples and the samples are considered RNase free.



Lane (a) test of the submitted products, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control. **Deoxyribonuclease (DNase):** 

ViaPure lots are tested for DNase and are free of any detectable DNase contamination.

Products are tested for DNase activity by the following protocol:

Products are extracted in DNase free water. The extract was then added to a DNA standard. The DNA standard was incubated at 37°C for 1 hour and then heated to 65°C for 5 minutes. DNA samples were then run on an agarose gel, photographed and evaluated for degradation. No visible degradation was present in the product samples. Therefore the products are considered DNase Free.



Lane (a) test of the submitted products, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

