

April 2, 2014

NagorLtd,  
129 Deerdykes View,  
Westfield Ind. Estate,  
Cumbernauld,  
Glasgow,  
G68 9HN

Dear Mr. Barsanti,

Applied Silicone is a global supplier of implantable grade silicone material for medical devices. The company has over 25 years' experience in supplying the medical device and breast implant industry. Applied Silicone products are designed to meet FDA and ISO 10993 biocompatibility guidelines. We presently have over 30 Master Files with the FDA. We are ISO 90001:2008 certified. We pride ourselves on our expertise in device manufacture and in particular the manufacture of breast implants.

We presently supply Nagor with two distinct dispersions for the manufacture of breast implants and other medical devices; Fluorosilicone Barrier dispersion (PN- 40130) which is dispersed in PCE/BA and a Dimethyl Silicone Elastomer (PN-40000) which is dispersed in Xylene. The use of the specific solvents allows for a consistent coating of the mandrel. In our extensive experience we have not found nor do we presently disperse any product in a different solvent other than PCE/BA or Xylene.

As you begin to deviate from the prescribed solvents, manufacturability will be lost as an alternative solvent may not poses similar dispersing properties. Solvents which theoretically poses similar dispersion qualities tend to be highly flammable and pose a very significant Health & Safety risk. Applied Silicone's facility is not presently rated to handle such solvents and we believe the H & S risks coupled with other detrimental features in its use mean this will not happen in the future.

If you have any questions or you would like any clarification, please do not hesitate in contacting me.

Yours Sincerely,



Enda Heery  
International Sales & Technical Director