



**VALUE PLASTICS, INC.**  
SPECIALISTS IN FLUID CONNECTIONS™

July 1, 2011

**Re: Regulatory Status of Value Plastics Products**

To Whom It May Concern:

Under the FDA's good manufacturing practices (GMP) quality system (QS) regulations as noted in 21 CFR 820, Value Plastics is considered a component supplier (see 21 CFR 820.5 (c) for the definition.) Accordingly, there is no "regulatory status" for Value Plastics products.

Many resins used to manufacture Value Plastics products have been tested to U.S.P. Class VI and / or ISO 10993 procedures, acceptance criteria common in medical device applications. For further resin information, please copy and paste the following link into your browser's address window:

[http://www.valueplastics.com/tech/material\\_data.aspx](http://www.valueplastics.com/tech/material_data.aspx)

Please contact me with any further questions you may have. Thank you for your interest in Value Plastics products.

**Rogel Balbuena**

Quality Assurance and Regulatory Affairs Manager

