



NEW BJP CONCENTRATOR OFFERINGS

Dear Valued Customer,

Vivaproducts would like to announce a new option for our BJP concentrator products. As most of you know, the BJP concentrators have traditionally been labeled for *in vitro* diagnostic (IVD) use. This was done primarily to comply with FDA regulations in the United States. However, the new IVD Regulation 2017/746 (IVDR) in the European Union (EU) countries caused us to examine other alternatives for labeling.

After a review of these regulations, Vivaproducts has determined that the BJP concentrators should be classified as General Laboratory Use (GLU) products as defined by the IVDR classification rules. The BJP products are supplied non-sterile and do not provide measurements in any diagnostic tests as IVD products do. The BJP products were originally designed as laboratory sample concentrators and not specifically for diagnostic applications. It should be noted that other benchtop sample concentrators are also being classified and labeled as GLU products.

These GLU BJP products have the same Item Numbers as before except the letter “G” appears at the end and all prices are the same. We will continue to offer our current IVD labeled BJP products for use in countries with different regulations and other classification methods. Please contact me at btutunjian@vivaproducts.com for any questions on this topic.

Sincerely,

Robert Tutunjian
President

