

MicroBioLogics

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Prior to December of 2003 products, such as MicroBioLogics' reference stock culture microorganism preparations, which are marketed and distributed within the European Economic Area must be identified with the CE-Mark. The CE-Mark provides testimony that the products meet the requirements of the "***In Vitro Diagnostic Directive***" and conform to criteria for placing in vitro diagnostic medical devices on the European market.

On April 25, 2002, MicroBioLogics had completed and conformed to the CE-Mark requirements for their reference stock culture products. With the self-declaration process being completed, we have begun to distribute **LYFO-DISK®**, **KWIK-STIK™**, and **KWIK-STIK™ Plus Microorganisms** with the CE-Mark.

The transition period for the complete CE labeling and instructions of these products is in process. MicroBioLogics requires over 2,500 catalog numbers to identify all its products. Although you may have begun to receive only some CE-Mark products, the transition process to achieve complete CE labeling and instructions for the **LYFO-DISK®**, **KWIK-STIK™**, and **KWIK-STIK™ Plus Microorganisms** is scheduled to be completed prior to December 2003. Also, the CE-Mark will not be limited to products distributed into the European market. All reference stock culture products regardless of their domestic or international destination will carry the CE-Mark.

The Assayed Product lines of MicroBioLogics that include **EZ-CFU™**, **EZ-FPC™**, **EZ-PEC™** and **E^{power}™ Microorganisms** are intended for industrial applications only. Based on the fact that the above stated products are not intended for clinical applications and are not actually used for establishing or verifying performances of medical devices, they do not fall under the definition of "in vitro diagnostic medical devices" as defined in the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostics medical devices. Therefore, the requirements of this directive, including the CE Mark, do not apply to the above stated products. MicroBioLogics will be able to ship internationally without the CE Mark after December 7, 2003 for the above stated Assayed Product lines.

We have also recognized the need for product insert translations regardless of the CE Mark requirements for our Assayed Product line. MicroBioLogics is dedicated and very sensitive to meeting the needs of their customers. In the very near future, the product insert translations for both MicroBioLogics Assayed Product line as well as our CE-Marked Reference Stock Culture product line will be available on our web site.

The CE-Mark is a regulatory directive to which MicroBioLogics' CE Marked products conform. Any company or organization that markets, sells and distributes similar products into the European Market must also conform.

This conformity also offers confirmation that MicroBioLogics' quality management system will continue to ensure quality products and quality services. MicroBioLogics' CE-Mark together with its ISO 9001:2000 Company Certificate of Registration is a competitive advantage.

Thank you for your continued support and for extending the opportunity to MicroBioLogics to serve your needs.

Submitted for the Record

Danette Then
MicroBioLogics
Executive Representative
Compliance Officer