

DECLARATION OF CONFORMITY

Corporate Office: Quidel Corporation
10165 McKellar Court
San Diego, California 92121
USA

Manufacturer: Quidel Corporation
Northern California Operations
2981 Copper Road
Santa Clara, California 95051
USA

Product Name: Metra™ BAP EIA Kit

Description: The Metra™ BAP immunoassay provides a quantitative measure of bone-specific alkaline phosphatase (BAP) activity in serum as an indicator of osteoblastic activity. Measurement of BAP is intended for use as an aid in the management of postmenopausal osteoporosis and Paget's disease; monitoring of postmenopausal women on hormonal or bisphosphonate therapy; and prediction of skeletal response to hormonal therapy in postmenopausal women.

Classification: **Annex III of EC Council Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices**

Estimated Start of CE-Marking: **December 19, 2003**

Quidel Corporation, being the manufacturer within the European Economic Area, hereby declares that the products covered by the declaration conform with the Essential Requirements of EC Directive 98/79/EC. Supporting documentation is retained under the premises of the manufacturer.

Signed _____



Date 12/19/03

Julie Blacklock
Manager, QA and Regulatory Affairs Specialist
Northern California Operations