

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™ Osteocalcin EIA Kit

Description: The Metra™ Osteocalcin immunoassay quantitatively measures intact (*de novo*) osteocalcin in serum. Intact osteocalcin may be useful as a biochemical indicator of bone turnover.

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

Estimated Start of CE-Marking: **January 16, 2004**

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 _____

1/16/2004

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