

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™ DPD EIA Kit

Description: Metra™ DPD is a urinary assay that provides a quantitative measure of the excretion of deoxypyridinoline (DPD) crosslinks as an indicator of bone resorption. Elevated levels of urinary DPD indicate elevated bone resorption in individuals. Measurement of DPD is intended for use as an aid in monitoring bone resorption changes in postmenopausal women receiving hormonal or bisphosphonate antiresorptive therapies and in individuals diagnosed with osteoporosis.

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