

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: **MicroVue™ Osteocalcin EIA Kit**

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

Classification: **Article 9, paragraph 1 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 Rebecca Ramirez
Rebecca Ramirez
Quality Assurance / Regulatory Affairs Analyst
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Date 10/14/09