

DECLARATION OF CONFORMITY

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

Manufacturer: Quidel Corporation
Specialty Products Group
2981 Copper Road
Santa Clara, California 95051
USA

Product Name: **MicroVue™ TRAP5b EIA Kit**

Description: The MicroVue™ TRAP5b Assay is an immunocapture enzyme assay for determination of tartrate-resistant acid phosphatase isoform 5b (TRAcP 5b). TRAP5b is secreted in serum by bone resorbing osteoclasts and is an indicator of osteoclast activity *in vivo*. Levels of TRAP5b activity may be a useful indicator of osteoclast activity and hence bone resorption in primary osteoporosis and other diseases.

Classification: **Article 9, paragraph 1, of EC Council Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices**

Estimated Start of CE-Marking: **February 22, 2006**

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 _____



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