

## 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™ CICIP EIA Kit

**Description:** Collagen, the triple-helical molecule which forms the fibrous framework of all connective tissues, is synthesized as procollagen, a larger precursor molecule. Procollagen consists of mature collagen with extension peptides at both the amino and carboxy termini. These extension peptides, or propeptides, are cleaved from the collagen molecule by specific proteases prior to incorporation of collagen into a growing collagen fibril. The release of these peptides into the circulation provides a stoichiometric representation of the production of collagen.

**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