Declaration of Conformity Certificate

We

ACON Laboratories, Incorporated 4108 Sorrento Valley Boulevard San Diego, CA 92121

ensure and declare with sole responsibility, that our In Vitro Diagnostic Medical Devices:

ACON One Step Myoglobin/CK-MB/Troponin I Combo Test Device (Whole Blood/Serum/Plasma) CMA-435

meet the provisions of Council Directive 98/79/EC which apply to us. This declaration is based on approval according to Annex III (excluding III.6)

Authorized Representative:
Medical Device Safety Service (MDSS)
Burckhardtstrasse 1
D - 30163

Signed this day 11 th of March 2005

Susan E. Martyn

Management Representative Quality Systems Manager ACON Laboratories, Inc.