

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:**

On•Call Strep A Rapid Test Strip
On•Call Strep A Rapid Test Device
On•Call Strep A Twist Rapid Test Device

**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)**

We hereby appoint MDSS, Burckhardtstrasse 1, D - 30163 Hannover, Germany to act as
Authorised Representative as stipulated in Art. 10.3 of the In Vitro Diagnostic Medical Device
Directive 98/79/ EC.

Signed this day 18th of November 2003


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Susan E. Martyn
Management Representative
Quality Systems Manager
ACON Laboratories, Inc.