Section 4

Declaration of Conformity

Manufacturer Address	Bio-Rad Laboratories 9500 Jeronimo Road Irvine, CA 92618
European Representative	Bio-Rad 3, Boulevard Raymond Poincare Marnes-La-Coquette FRANCE 92430
Products/ Model Code	Liquichek™ Urinalysis Control

Product	Catalog Number
Liquichek™ Urinalysis Control Bilevel	435
Liquichek™ Urinalysis Control Level 1	436
Liquichek™ Urinalysis Control Level 2	437

Classification: Non-listed (In-Vitro Diagnostic Directive, Annex II)

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supplying documentation is retained under the premises of the manufacturer and the notified body.

DIRECTIVES

General applicable directives:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Standards:

Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are: 98/79/EC: 1998, EN ISO 13485:2000, EN 980: 2003, EN 1441:1997, EN 928:1995, ISO 14971:2001, EN 13641:2002, EN 13612:2002, EN 13640:2002, 88/379/EEC: 2003, 67/548/EEC: 1967.

Notified Body: TÜV Rheinland Product Safety, GmbH
World Headquarters
Am Grauen Stein
Konstantin-Wille-Straße 1
D - 51105 Cologne

Signature: Frieda Casey
Name: Frieda Casey
Date: 4/30/03
Position: Regulatory Affairs Specialist