

Section 4

Declaration of Conformity

Manufacturer Bio-Rad Laboratories
Address 9500 Jeronimo Road
Irvine, CA 92618

European Bio-Rad
Representative 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

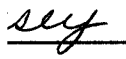
General applicable directives:

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