

## Declaration of Conformity

(in accordance with standard EN 45014:1998)

Manufacturer Eurotrol B.V.  
Keplerlaan 20  
6716 BS Ede  
The Netherlands

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Product family 146  
Eurotrol GlucoTrol-NG

Product(s)	<u>Product Code</u>	<u>Description</u>
	146.001.002	GlucoTrol-NG - Level 1
	146.002.002	GlucoTrol-NG - Level 2
	146.003.002	GlucoTrol-NG - Level 3
	146.004.002	GlucoTrol-NG - Level 4
	146.005.002	GlucoTrol-NG - Level 5

First batch number Level 1: 61360  
conform IVD Level 2: 61361  
Level 3: 61362  
Level 4: 61363  
Level 5: 61364

These products comply with the provisions of "Besluit in-vitro diagnostica", the transposition of the In Vitro Diagnostic Medical Device Directive (98/79/EEC)

- Method of Assessment: Self-Assessment according to ANNEX III

These products are manufactured conform our procedures that meet the following Quality Management Systems:

<u>Quality Management System</u>	<u>Date of issue</u>
ISO 9001:2000	2000
EN-ISO 13485:2003	2006



*Your Global Reference Point for Quality Control*

Declared by Ede, 21-6-2006

A blue ink signature of Paul B.P. Kooijmans, written in a cursive style.

Paul B.P. Kooijmans  
Quality Assurance Manager

A blue ink signature of Bart H. Maas, written in a cursive style.

Bart H. Maas  
Managing Director