

CE Registration Certificate

This is to certify that, in accordance with the In Vitro Diagnostic Medical Device Directive 98/79/EC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

Teco Diagnostics 1268 N. Lakeview Avenue Anaheim, CA 92807 USA

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received the In Vitro Diagnostic Medical Device Registrations on the following dates:

See Annex A Dated 28 April 2008

Emergo Europe Registration Number: NL/CA01/601529

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the In Vitro Diagnostic Medical Devices fulfill the applicable requirements of Directive 98/79/EC.

28 April 2008

Rene van de Zande President Emergo Europe



EmergoEurope.com



Annex A to the Emergo Europe CE Registration Certificate dated 28 April 2008

Austria, Belgium, France, Germany, Greece, Iceland, Italy, Netherlands, Portugal, Spain, Sweden, and the United Kingdom have received registrations for the following products:

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
Urine Reagent Strips (for specific products, see attached product listing)	11.70.02.01.00	Other devices Self-declared	December 2002
Clinical Chemistry Reagents (for specific products, see attached product listing)	Varies—see attached listing	Other devices Self-declared	December 2003
Clinical Serology Reagents (for specific products, see attached product listing)	Varies—see attached listing	Other devices Self-declared	December 2003

Malta, Poland, Romania, Lithuania, Latvia, and Switzerland have received registrations for the following products:

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
Clinical Chemistry Reagents (for specific products, see attached product listing)	Varies—see attached listing	Other devices Self-declared	May, 2005

Austria, Belgium, France, Germany, Greece, Iceland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Romania, Spain, Sweden, Switzerland, and the United Kingdom have received registrations for the following products:

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
Urine Strip Reader Uritek 151 Uritek 720	21 01 10 01	Other devices Self-declared	March, 2006



France, Germany, Greece, Italy, Netherlands, Poland, Portugal, Spain and United Kingdom have received registrations for the following products:

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
Micro-Albumin 2-1 Combo Strips	11 70 02 01	Other devices Self-declared	July, 2007
TC-Matrix Chemistry Analyzer	21 01 10 01		

Bulgaria, Czech Republic, Italy, Netherlands, and Portugal have received registrations for the following products:

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
Uritek TC-101	29 01 10 01	Other devices Self-declared	March, 2008

Poland has received registrations for the following products:

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
Uritek TC-101	29 01 10 01	Other devices Self-declared	April, 2008