



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

**Association of Medicine and Analytics Co. Ltd.
17 line of Vasilievsky Island
4-6, 199034, Saint Petersburg
Russia**

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 attached product listing

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.

July 2010



Rene van de Zande
President
Emergo Europe



Annex A to the Emergo Europe CE Registration Certificate

dated July 2010

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
HELIC Ammonia Breath Test HELIC (ABT)	15.70.01.02	Other (Self-Declaration)	23 July 2010 – Finland, France, Germany, Lithuania, Poland, the Netherlands
Helicobacter pylori AMA RAPID UREASE TEST	15.70.01.02	Other (Self-Declaration)	23 July 2010 – Finland, France, Germany, Lithuania, Poland 24 February 2010 – The Netherlands