



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 98/79/EC	Registration Date
HELIC Ammonia Breath Test	15.70.01.02	Other (Self-Declaration)	23 July 2010 – Finland,
HELIC (ABT)			France, Germany, Lithuania,
			Poland, the Netherlands
Helicobacter pylori AMA	15.70.01.02	Other (Self-Declaration)	23 July 2010 – Finland,
RAPID UREASE TEST			France, Germany, Lithuania,
(AMA RUT)			Poland
			24 February 2010 – The
			Netherlands