



# 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

**Abbott Point of Care Inc.  
400 College Road East  
Princeton, NJ 08540  
U.S.A.**

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.

October 2011



Rene van de Zande  
President & CEO  
Emergo Europe



## Annex A to the Emergo Europe CE Registration Certificate

dated October 2011

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
i-STAT® 1 Analyzer	21.07.10.09	Other (Self-Certify)	September 2003
i-STAT Calibration Verification Set Levels 1-5	11.50.90.90	Other (Self-Certify)	September 2003
i-STAT Control Level 1	11.50.90.90	Other (Self-Certify)	September 2003
i-STAT Control Level 2	11.50.90.90	Other (Self-Certify)	September 2003
i-STAT Control Level 3	11.50.90.90	Other (Self-Certify)	September 2003
i-STAT® 1 Downloader- Network	21.07.10.09	Other (Self-Certify)	September 2003
i-STAT 6+ Cartridge	11.30.04.11	Other (Self-Certify)	September 2003
i-STAT 65uL Capillary Dispensers	51.01.01.03	Other (Self-Certify)	September 2003
i-STAT ACT Control Level 1	13.02.50.02	Other (Self-Certify)	September 2003
i-STAT ACT Control Level 2	13.02.50.02	Other (Self-Certify)	September 2003
i-STAT Analyzer Programming Kit	21.07.10.09	Other (Self-Certify)	September 2003
i-STAT Celite® ACT Cartridge	13.02.01.04	Other (Self-Certify)	September 2003
i-STAT CG4+ Cartridge	11.30.04.11	Other (Self-Certify)	September 2003
i-STAT CG8+ Cartridge	11.30.04.11	Other (Self-Certify)	September 2003
i-STAT Crea Cartridge	11.04.03.01	Other (Self-Certify)	September 2003
i-STAT® 1 Downloader- Serial	21.07.10.09	Other (Self-Certify)	September 2003
i-STAT E3+ Cartridge	11.30.04.03	Other (Self-Certify)	September 2003
i-STAT EC4+ Cartridge	11.30.04.11	Other (Self-Certify)	September 2003
i-STAT EC8+ Cartridge	11.30.04.11	Other (Self-Certify)	September 2003
i-STAT EG6+ Cartridge	11.30.04.11	Other (Self-Certify)	September 2003
i-STAT EG7+ Cartridge	11.30.04.11	Other (Self-Certify)	September 2003
i-STAT Electronic Simulator	21.07.10.09	Other (Self-Certify)	September 2003
i-STAT G3+ Cartridge	11.30.04.04	Other (Self-Certify)	September 2003
i-STAT G Cartridge	11.04.03.02	Other (Self-Certify)	September 2003
i-STAT IR Link	21.07.10.09	Other (Self-Certify)	September 2003
i-STAT Portable Clinical Analyzer	21.07.10.09	Other (Self-Certify)	September 2003
i-STAT Printer Cradle	Not available	Other (Self-Certify)	September 2003
i-STAT PT Control Level 1	13.02.50.02	Other (Self-Certify)	September 2003
i-STAT PT Control Level 2	13.02.50.02	Other (Self-Certify)	September 2003
i-STAT Kaolin ACT Cartridge	13.02.01.04	Other (Self-Certify)	September 2003
i-STAT Prothrombin Time Cartridge	13.02.01.01	Other (Self-Certify)	September 2003
i-STAT Downloader/Recharger – Serial and Network	21.07.10.09	Other (Self-Certify)	May 2005
i-STAT 1 9V NiMH Battery	21.07.10.09	Other (Self-Certify)	May 2005
i-STAT BNP Cartridge	12.13.01.01	Other (Self-Certify)	December 2006
i-STAT BNP Control Level 1	12.50.01.08	Other (Self-Certify)	December 2006



i-STAT BNP Control Level 2	12.50.01.08	Other (Self-Certify)	December 2006
i-STAT BNP Control Level 3	12.50.01.08	Other (Self-Certify)	December 2006
i-STAT BNP Calibration Verification Set Levels 1-3	12.50.01.08	Other (Self-Certify)	December 2006
i-STAT CHEM8+Cartridge	11.30.04.11	Other (Self-Certify)	December 2006
i-STAT CHEM8+Control Level 1	11.50.90.90	Other (Self-Certify)	December 2006
i-STAT CHEM8+Control Level 2	11.50.90.90	Other (Self-Certify)	December 2006
i-STAT CHEM8+Control Level 3	11.50.90.90	Other (Self-Certify)	December 2006
i-STAT CHEM8 + Calibration Verification Level 1b	11.50.90.90	Other (Self-Certify)	December 2006
i-STAT CHEM8 + Calibration Verification Set Levels 1-5	11.50.90.90	Other (Self-Certify)	December 2006
i-STAT CK-MB Cartridge	12.13.01.02	Other (Self-Certify)	December 2006
i-STAT Printer	21.07.10.09	Other (Self-Certify)	October 2011
i-STAT PT/INR Cartridge	13.02.01.01	Other (Self-Certify)	October 2011
i-STAT cTnl Cartridge	12.13.01.07	Other (Self-Certify)	October 2011
i-STAT Cardiac Markers Control Level 1	12.50.01.08	Other (Self-Certify)	October 2011
i-STAT Cardiac Markers Control Level 2	12.50.01.08	Other (Self-Certify)	October 2011
i-STAT Cardiac Markers Control Level 3	12.50.01.08	Other (Self-Certify)	October 2011
i-STAT Cardiac Markers Calibration Verification Control Set Levels 1-3	12.50.01.08	Other (Self-Certify)	October 2011