

Declaration of Conformity

Legal Manufacturer's Name:	Abbott Point of Care Inc.
Legal Manufacturer's Address:	100 and 200 Abbott Park Rd.
	Abbott Park, IL 60064
	United States of America
Legal Manufacturer's Telephone & Fax:	Tel: +1 609 454-9000
	Fax: +1 609 419-9370

Catalogue Numbers (REF) of Devices	Device Name	Classification
02R60-01	i-STAT Alinity Instrument (Model No. AN-500)	Self-declared
02R63-01	i-STAT Alinity Battery (Model No. RB-500)	Self-declared
02R62-01	i-STAT Alinity Electronic Simulator (Model No. ES-500)	Self-declared
02R61-01	i-STAT Alinity Base Station (Model No. BST-500)	Self-declared
02R61-04	i-STAT Alinity Charge Station (Model No. CS-500)	Self-declared
02R64-05	i-STAT Alinity Printer Kit	Self-declared
04P75-01	i-STAT 1 Analyzer (Model No 300-G)	Self-declared
03P75-06	i-STAT 1 Wireless Analyzer (Model No 300W)	Self-declared
06F11-01	i-STAT Electronic Simulator	Self-declared
04P74-04	i-STAT Printer Kit	Self-declared
04P73-04	i-STAT 1 Downloader Recharger (Model No. DRC-300)	Self-declared
06F23-55	i-STAT 1 9V NiMH Battery	Self-declared
03P83-25	i-STAT G Cartridge	Self-declared
03P82-25	i-STAT E3+ Cartridge	Self-declared
03P80-25	i-STAT 6+ Cartridge	Self-declared
03P81-25	i-STAT EC4+ Cartridge	Self-declared
03P79-25	i-STAT EC8+ Cartridge	Self-declared
03P78-25, 03P78-50	i-STAT G3+ Cartridge	Self-declared
03P77-25	i-STAT EG6+ Cartridge	Self-declared
03P76-25	i-STAT EG7+ Cartridge	Self-declared
03P84-25	i-STAT CREA Cartridge	Self-declared
03P85-25, 03P85-50	i-STAT CG4+ Cartridge	Self-declared
03P88-25	i-STAT CG8+ Cartridge	Self-declared
03P86-25	i-STAT Celite® ACT Cartridge	Self-declared
03P87-25	i-STAT Kaolin ACT Cartridge	Self-declared

Catalogue Numbers (REF) of Devices	Device Name	Classification
03P89-24	i-STAT PT/INR Cartridge	Self-declared
03P8950	i-STAT PT ^{plus} Cartridge	Self-declared
03P90-25, 06P23-25	i-STAT cTnl Cartridge	Self-declared
09P31-25	i-STAT CHEM8+ Cartridge	Self-declared
03P92-25	i-STAT CK-MB Cartridge	Self-declared
03P93-25	i-STAT BNP Cartridge	Self-declared
05P58-25	i-STAT Total β -hCG Cartridge	Self-declared
06F12-01	i-STAT Control Level 1	Self-declared
06F13-01	i-STAT Control Level 2	Self-declared
06F14-01	i-STAT Control Level 3	Self-declared
06F15-01	i-STAT Calibration Verification Set Levels 1-5	Self-declared
06P17-15	i-STAT ACT Control Level 1	Self-declared
06P17-16	i-STAT ACT Control Level 2	Self-declared
06P17-13	i-STAT PT Control Level 1	Self-declared
06P17-14	i-STAT PT Control Level 2	Self-declared
06P17-17	i-STAT PT ^{plus} /aPTT Control Level 1	Self-declared
06P17-18	i-STAT PT ^{plus} /aPTT Control Level 2	Self-declared
06P17-09	i-STAT cTnl Control Level 1	Self-declared
06P17-10	i-STAT cTnl Control Level 2	Self-declared
06P17-11	i-STAT cTnl Control Level 3	Self-declared
06P17-12	i-STAT cTnl Calibration Verification 1-3	Self-declared
06P17-01	i-STAT CK-MB Control Level 1	Self-declared
06P17-02	i-STAT CK-MB Control Level 2	Self-declared
06P17-03	i-STAT CK-MB Control Level 3	Self-declared
06P17-04	i-STAT CK-MB Calibration Verification 1-3	Self-declared
06F12-14	i-STAT CHEM8+ Calibration Verification Level 1b	Self-declared
06P17-05	i-STAT BNP Control Level 1	Self-declared
06P17-06	i-STAT BNP Control Level 2	Self-declared
06P17-07	i-STAT BNP Control Level 3	Self-declared
06P17-08	i-STAT BNP Calibration Verification Set Levels 1-3	Self-declared
05P71-01	i-STAT TriControls Control Level 1	Self-declared
05P72-01	i-STAT TriControls Control Level 2	Self-declared
05P73-01	i-STAT TriControls Control Level 3	Self-declared
05P70-01	i-STAT TriControls Calibration Verification Set Levels 1-5	Self-declared
02R29-01	i-STAT Total β -hCG Control Level 1	Self-declared

Catalogue Numbers (REF) of Devices	Device Name	Classification
02R29-02	i-STAT Total β -hCG Control Level 2	Self-declared
02R29-03	i-STAT Total β -hCG Control Level 3	Self-declared
05P59-04	i-STAT Total β -hCG Calibration Verification Set	Self-declared

Authorized European Representative (name and address)¹ (Telephone) (Fax)	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands +31 70 345 8570 +31 70 346-7299
Storage of technical documentation (name and address)	Abbott Point of Care Inc., 400 College Road East Princeton, NJ 08540 USA
Harmonized Standards	Listed in the Technical Documentation

¹Previously located at: Molenstraat 15, 2513 BH The Hague, The Netherlands

I, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of:

- Annex III of the IVD Directive 98/79/EC as they are transposed into the laws of the member states
- European Union Directive 2011/65/EU – RoHS
- 2014/53/EU RE Directive (Models 300W and AN-500 only)
 - EN 300 328 V2.1.1
 - EN 301 893 V2.1.0 (Model AN-500 only)
 - EN 301 489-1 V2.1.1
 - EN 301 489-17 V3.1.1

and is issued under the sole responsibility of the manufacturer.

Signature: 

Date: 06-Nov-2018

Full Name (printed): **Susan Tibedo**

Position: **Director, Regulatory Affairs**

Effective Date: 06-Nov-2018

Supersedes: **03-Aug-2018**

i-STAT is a registered trademark of Abbott group of companies in various jurisdictions.
