

## Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/Number	Catalog number
epoc Blood Analysis System	epoc Reader epoc Host epoc BGEM Test Card epoc Care-Fill Capillary Tube	Annex 1 CE Marked Products

MANUFACTURER			
Name of company	Address		Representative
	Head office	Secondary Manufacturing Location	
Epocal Inc.	2060 Walkley Road Ottawa K1G 3P5 Canada	855 Brookfield Road, Suite 101, Ottawa, Ontario, K1V 2S5 Canada	George Papadopoulos Sr. Manager, Quality Assurance

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	IEC61010-1, IEC61010-2-81, IEC61010-2-101, IEC61326-1, IEC61326-2-6, ISO13485, ISO14971

Epocal Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 98/79/EC and RoHS Directive 2011-65/EU as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** George Papadopoulos

**TITLE:** Sr. Manager, Quality Assurance

**SIGNATURE:**

**DATE:** 22 February 2018



## Annex 1

### CE Marked Products

<b>epoc Host</b>	<b>Catalogue Number</b>	<b>Description</b>
	HH-1009-00-00	epoc Host, Motorola
	HH-1R09-00-00	epoc Host, Motorola, Refurbished
<b>epoc Reader</b>	HR-1002-00-00	epoc Reader
	HR-1R04-00-00	epoc, Reader, Refurbished RoHS compliant
<b>epoc BGEM Test Card</b>	CT-1004-00-00	epoc BGEM Test Card (w. Glucose & Lactate)
	CT-1006-00-00	epoc BGEM Test Card (w. Creatinine & Chloride)
<b>epoc Care-Fill Capillary Tube</b>	AT-0006-00-00	Capillary Tube, Care-Fill, Bundle of 50