

## EU Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/Number	Catalog number
<b>epoc® Blood Analysis System</b>	epoc Reader epoc Host 2 epoc NXS Host epoc BGEM Test Cards epoc Care-Fill Capillary Tubes	Annex 1 CE Marked Products

LEGAL MANUFACTURER <sup>1</sup>		
Name of company	Address	Representative
	Head office	
<b>Epocal Inc.</b>	2060 Walkley Road Ottawa K1G 3P5 Canada	Sarah Lavoie Director, Quality Assurance

PLACE OF MANUFACTURE		
Name of company	Address	epoc Reader, Host 2, NXS Host and Care-Fill Capillary Tubes
	epoc BGEM Test Cards	
<b>Epocal Inc.</b>	2060 Walkley Road Ottawa, ON K1G 3P5 Canada	855 Brookfield Road, Suite 101 Ottawa, ON K1V 2S5 Canada

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/Email
<b>Emergo Europe</b>	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone <a href="mailto:EmergoEurope@ul.com">EmergoEurope@ul.com</a>

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 (EU) 2015/863 as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Sarah Lavoie

**TITLE:** Director, Quality Assurance

**SIGNATURE and Date:**



Electronically  
signed by: SARAH  
LAVOIE  
Reason: I am  
approving this  
document  
Date: Jul 20, 2021  
08:50 EDT

<sup>1</sup> Legal Manufacturer address is applicable to all products within the scope of this Declaration of Conformity.

## Annex 1

### CE Marked Products

<b>epoc Host 2</b>	<b>SMN</b>	<b>Catalogue Number</b>	<b>Description</b>
	10736387	HH-1009-00-00	epoc Host 2 (Zebra MC55A)
	10736393	HH-1R09-00-00	epoc Host 2 (Zebra MC55A), Refurbished
	11413528	11413528	epoc Host 2 (Zebra MC55X)
	11413602	11413602	epoc Host 2 (Zebra MC55X), Refurbished
<b>epoc NXS Host</b>	11413497	11413497	epoc NXS Host - 0000 - EU
	11413518	11413518	epoc NXS Host - 544D - RoW
<b>epoc Reader</b>	10736398	HR-1002-00-00	epoc Reader
	10736404	HR-1R04-00-00	epoc Reader, Refurbished RoHS compliant
<b>epoc BGEM Test Cards</b>	10736382	CT-1006-00-00	epoc BGEM Test Card (w. Creatinine & Chloride)
	10736515	10736515	epoc BGEM Test Cards (w. BUN and TCO2)
<b>epoc Care-Fill Capillary Tubes</b>	10736380	AT-0006-00-00	epoc Care-Fill Capillary Tubes