EU DECLARATION OF CONFORMITY

Manufacturer	
Name:	Epocal Inc.
Address:	2060 Walkley Road, Ottawa, Ontario K1G 3P5, Canada
Single Registration Number (SRN):	CA-MF_000017182
Authorized Representative	
Name:	Siemens Healthcare Diagnostics Ltd.
Address:	Chapel Lane Swords, Co. Dublin, Ireland
SRN Authorized Representative:	IE-AR-000006763
Manufacturing Facility	
Name:	Epocal Inc.
Address:	2060 Walkley Road, Ottawa, Ontario K1G 3P5, Canada
Product Identification	see Product Identification Table

We declare that the in vitro diagnostic medical device(s) listed in the Product Identification table is/are in conformity with the following legislation(s):

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

The conformity of the quality management system according to Annex IX and Article 48 is certified by the following notified body:

TUV Rheinland
LGA Products GmbH
TillystraBe 2, 90431 Nurnberg

The identification number of the notified body for implementation of the procedure set out in Annex IX to the above regulation is: 0197
Certificate number: IX 2262557-1

Reference to Applied Standards:

ISO 13485:2016	*Quality System for Medical Devices*
EN 13612:2002	*Performance Evaluation if In-Vitro Medical Devices*
EN 23640:2015	*Evaluation of Stability Testing of In-Vitro Diagnostic Reagents*
ISO 15223-1:2016	*Symbols to be Used with Medical Device Labels, labeling and information to be supplied Part 1 General Requirements*
ISO 15223-2:2010	*Symbols to be used with medical device labels, labeling and information to be supplied Part 2 Symbol development, selection and validation*
ISO 14971:2019	*Medical Devices Application of Risk Management to Medical Devices*
ISO 18113-1:2011	*IVD Information Supplied by the Manufacturer (Labeling) - Part* ISO
18113-2:2009	*IVD Information Supplied by the Manufacturer (Labeling) – Part 2*

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Relevant Harmonized Standard:	*EN 50581:2012* *EN IEC 63000:2018*

This declaration of conformity is issued under the sole responsibility of *Siemens Healthcare Diagnostics Inc.*

This declaration supersedes any declaration issued previously for the same products.

On Behalf of Epocal Inc. (A Siemens Healthineers Company):

Place and date Ottawa, Ontario, April 3, 2023

Electronically signed by: Jim Novesteras
Reason: I am approving this document
Date: Apr 3, 2023 17:43 EDT

Jim Novesteras
Regulatory Affairs Senior Technical Specialist
Operations

For conditions of warranty and liability please refer to the General Conditions of Sale.

Product Identification Table

Product/Trade Name	Model	REF	Basic UDI-DI	Risk Class	Intended Purpose
epoc® BGEM Test Cards	10736382 10736515	CT-1006-00-00 10736515	0405686901913VY	*Class C – Annex VIII 2.3 Rule 3(k)*	The **epoc® Blood Analysis System** is intended for use by trained medical professionals as a semi-automated in vitro diagnostic device for the quantitative testing of human samples of heparinized or unanticoagulated arterial, venous, or capillary whole blood in the laboratory or at the point of care. The **Blood Gas Electrolyte and Metabolite (BGEM) Test Card** panel configuration includes sensors that quantitate pH, Carbon Dioxide (partial pressure), Oxygen (partial pressure), Sodium, Potassium, Ionized Calcium, Chloride, Total Carbon Dioxide, Glucose, Lactate, Blood Urea Nitrogen, Creatinine, and Hematocrit. **pH, *p*CO2, *p*O2 (blood gases)** measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of life-threatening acid-base disturbances. **Sodium** and **Potassium** measurements from the epoc Blood Analysis System are used in diagnosis and treatment of diseases involving electrolyte imbalance. **Ionized Calcium** measurements from the epoc Blood Analysis System are used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany. **Chloride** measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of electrolyte and metabolic disorders. **Total Carbon Dioxide** measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of disorders associated with changes in body acid-base balance. **Glucose** measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell tumors. **Lactate** measurements from the epoc Blood Analysis System are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood). **Blood Urea Nitrogen** measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal and metabolic diseases. **Creatinine** measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal diseases and in monitoring renal dialysis. **Hematocrit** measurements from the epoc Blood Analysis System are used to distinguish normal from abnormal states of blood volume, such as anemia and erythrocytosis.