

EU 2017/746 IVDR

Document #: REG-00088

Revision: 2

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

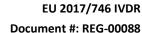
TillystraBe 2, 90431 Nurnberg

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

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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.

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Product/Trade Name	Model	REF	Basic UDI-DI	Risk Class	Intended Purpose
epoc® BGEM Test Cards	10736382	CT-1006-00-00 10736515	0405686901913V Y	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, pCO2, pO2 (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 acidbase 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.