

## Directive 98/79/EC, Annex III EC Declaration of Conformity

**Manufacturer:**

Diazyme Laboratories  
12889 Gregg Ct.  
Poway, CA 92064

Phone: 858-455-4768  
Fax: 858-455-4750

**Authorized Representative:**

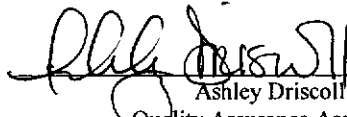
Medical Device Safety Service, GmbH  
Schiffgraben 41  
30175 Hannover  
Germany

**Models:**

See Attached List

We herewith declare that the below mentioned products meet the provisions of the EC Directive 98/79/EC which apply to them and all required standards of this directive. In addition, all applicable requirements of Annex III have been identified and fulfilled and are part of this declaration of conformity.

Issued on: 06/14/2013

  
Ashley Driscoll  
Quality Assurance Associate  
Diazyme Laboratories

## Directive 98/79/EC, Annex III

### EC Declaration of Conformity

DZ042A-C1V	TBA Level 1 (Low) Control
DZ042A-CAL	TBA Cycling Calibrator
DZ042A-CON	TBA Cycling Level 2 and Level 3 (High) Controls
DZ042A-K	Total Bile Acid (TBA) Enzymatic Test Kit
DZ042A-K01	Total Bile Acid (TBA) Enzymatic Test Half Kit
DZ042A-KB1	Total Bile Acid (TBA) Enzymatic Test Kit (Beckman Specific Packaging)
DZ042A-KH1	Total Bile Acid (TBA) Enzymatic Test Kit (Roche Hitachi Specific Packaging)
DZ042A-KY1	Total Bile Acids Enzymatic Cycling Test Kit (Olympus Specific Packaging)
DZ062A-CAL	(NAG) N-Acetyl- $\beta$ -D-glucosaminidase Calibrator Set
DZ062A-CON	(NAG) N-Acetyl- $\beta$ -D-glucosaminidase Control Set
DZ062A-K	N-Acetyl- $\beta$ -D-Glucosaminidase (NAG) Test Kit, (R1 & R2, liquid form)
DZ072B-CAL	Creatinine Enzymatic Calibrator Set
DZ072B-CON	Creatinine Enzymatic Control Set
DZ072B-K	Creatinine Enzymatic Test Kit, (R1 & R2, liquid form, endpoint)
DZ072B-KY1	Creatinine Enzymatic Test Kit, (Olympus Specific Packaging)
DZ082B-CAL	Alpha-L-fucosidase (AFU) Test Kit Calibrator (lyophilized)
DZ082B-CON	AFU Level 1 Control
DZ082B-K	Alpha-L-fucosidase (AFU) Test Kit, (single reagent, liquid form, endpoint)
DZ112B-CAL	Glycated Serum Protein Two (2) Level Calibrator Set
DZ112B-CON	Glycated Serum Protein Two (2) Level Control Set
DZ112B-K	Glycated Serum Protein Assay (GSP; Glycated Albumin) Test Kit, (liquid stable)
DZ113C-CAL	Enzymatic Potassium 2 Level Calibrator Set
DZ113C-CON	Enzymatic Potassium 2 Level Control Set (lyophilized)
DZ113C-K	Enzymatic Potassium Test Kit, (liquid stable)
DZ113C-K01	Enzymatic Potassium Half Kit, (liquid stable)
DZ114B-CAL	Enzymatic Sodium 2 Level Calibrator Set
DZ114B-CON	Enzymatic Sodium 2 Level Control Set
DZ114B-K	Enzymatic Sodium Test Kit, (liquid stable)
DZ114B-K01	Enzymatic Sodium Test Kit, (liquid stable)
DZ116B-CA5	Enzymatic Lithium 5 point Calibrator Set
DZ116B-CAL	Enzymatic Lithium Calibrator Set
DZ116B-CON	Enzymatic Lithium 2 Level Control Set
DZ116B-K	Enzymatic Lithium Assay (Liquid stable)
DZ116B-KB2	Enzymatic Lithium Assay (Liquid stable) for Beckman CXLX
DZ116B-KH1	Enzymatic Lithium Assay (Liquid stable) for Hitachi 917
DZ117A-CAL	Adenosine Deaminase Calibrator
DZ117A-CON	Adenosine Deaminase Control Set
DZ117A-K	Adenosine Deaminase (ADA) Test Kit, (R1 & R2, liquid form, rate)
DZ122A-CAL	Carbon Dioxide (CO <sub>2</sub> ) (405 nm) Calibrator
DZ122A-CON	Carbon Dioxide (CO <sub>2</sub> ) (405 nm) Control
DZ122A-K	Carbon Dioxide (CO <sub>2</sub> ) Test Kit (405nm) (single reagent, liquid stable)
DZ122A-KB1	Carbon Dioxide (CO <sub>2</sub> ) Test Kit (405nm) liquid stable, Beckman Specific Packaging
DZ122A-KY2	Carbon Dioxide (CO <sub>2</sub> ) Test Kit (405nm) liquid stable, Olympus Specific Packaging
DZ123A-CAL	5' - Nucleotidase (5' - NT) Calibrator
DZ123A-CON	5' - NT Control Set
DZ123A-K	5' - Nucleotidase Test Kit, (liquid stable)

## **Directive 98/79/EC, Annex III**

### **EC Declaration of Conformity**

DZ128A-K	LDL-Cholesterol Test Kit
DZ128A-KB1	LDL-Cholesterol Test Kit (Beckman Specific Packaging)
DZ128A-KY1	LDL-Cholesterol Test Kit (Olympus Specific Packaging)
DZ129A-K	HDL-Cholesterol Test Kit
DZ129A-KB1	HDL-Cholesterol Test Kit (Beckman Specific Packaging)
DZ129A-KY1	HDL-Cholesterol Test Kit (Olympus Specific Packaging)
DZ130A-CAL	HDL/LDL Cholesterol Calibrator (lyophilized)
DZ131A-CAL	Lp (a) Lipoprotein Five Level Calibrator Set
DZ131A-CON	Lp (a) Lipoprotein Control Set
DZ131A-K	Lp (a) Lipoprotein Test Kit
DZ131A-KB1	Lp (a) Lipoprotein Test Kit (Beckman Specific Packaging)
DZ131A-KY1	Lp (a) Lipoprotein Test Kit (Olympus Specific Packaging)
DZ132A-CAL	Lipase Calibrator Set
DZ132A-CON	Lipase Control Set
DZ132A-K	Lipase Test Kit (liquid stable)
DZ132A-KY1	Lipase Test Kit (Olympus Specific Packaging)
DZ133C-CAL	Cystatin C 5 Level Calibrator Set
DZ133C-CON	Cystatin C 2 Level Control Set
DZ133C-K	Cystatin C Test Kit
DZ133C-KB1	Cystatin C Test Kit (Beckman Specific Packaging)
DZ133C-KD1	Cystatin C Test Kit (Dade Sepcific Packaing)
DZ133C-KY1	Cystatin C Test Kit (Olympus Specific Packaging)
DZ133C-KY2	Cystatin C Test Kit (Olympus Specific Packaging)
DZ135A-CAL	hsCRP Calibrator Set (liquid)
DZ135A-CON	hsCRP Three (3) Level Control Set (liquid)
DZ135A-K	hsCRP Test Kit
DZ138A-CON	Multi-Analyte Lipid 3 Level Control Set
DZ141A-CAL	Apolipoprotein A-I/B Calibrator (lyophilized)
DZ141A-K	Apolipoprotein A-I (apo A) Test Kit (liquid stable)
DZ142A-K	Apolipoprotein B(apo B) Test Kit (liquid stable)
DZ145A-CAL	Troponin I Calibrator Set
DZ145A-CON	Troponin I Control Set
DZ145A-K	Troponin I Test Kit
DZ150A-CAL	Bilirubin Calibrator (lyophilized)
DZ150A-CON	Bilirubin Two (2) Level Control Set (lyophilized)
DZ150A-K	Total Bilirubin Test Kit
DZ151A-K	Direct Bilirubin Test Kit
DZ168A-CAL	Direct HbA1c Enzymatic Calibrator Set
DZ168A-CON	Direct HbA1c Enzymatic Control Set
DZ168A-K	Direct HbA1c Enzymatic Test Kit, (liquid stable)
DZ168A-KB1	Direct HbA1c Enzymatic Test Kit (Beckman Specific Packaging)
DZ168A-KD1	Direct HbA1c Enzymatic Test Kit (Dade Specific Packaging)
DZ168A-KY2	Direct HbA1c Enzymatic Test Kit, (Olympus Specific Packaging)

## **Directive 98/79/EC, Annex III**

### **EC Declaration of Conformity**

DZ179A-CAL	D-DimerCalibrator Set
DZ179A-CON	D-DimerControl Set
DZ179A-K	D-Dimer Test Kit
DZ568A-CA5	Enzymatic Homocysteine 5 Point Calibrator Set
DZ568A-CAL	Enzymatic Homocysteine Calibrator Set
DZ568A-CON	Enzymatic Homocysteine 4 Level Control Set
DZ568A-K	Enzymatic Homocysteine Test Kit
DZ568A-K03	Enzymatic Homocysteine Test Kit
DZ568A-K04	Enzymatic Homocysteine Test Kit (Beckman Specific Packaging)
DZ568A-K05	Enzymatic Homocysteine Test Kit (Beckman Specific Packaging)
DZ568A-K06	Enzymatic Homocystein Test Kit (Roche MODULAR P)
DZ568A-K07	Enzymatic Homocystein Test Kit (Roche MODULAR P)
DZ568A-KD2	Enzymatic Homocysteine Test Kit (Dade Specific Packaging)
DZ568AK06	Enzymatic Homocystein Test Kit (Roche MODULAR P barcoded)
DZ568AK07	Enzymatic Homocystein Test Kit (Roche MODULAR P barcoded)
DZ568B-BY1	Enzymatic Homocysteine Test Kit (Olympus Specific Packaging with barcode)
DZ568B-BY2	Enzymatic Homocysteine Test Kit (Olympus Specific Packaging with barcode)
DZ568B-CAL	Enzymatic Homocysteine Calibrator Set
DZ568B-K	Enzymatic Homocysteine Test Kit (2 reagents, liquid stable )
DZ568CAL	Enzymatic Homocysteine Calibrator Set (Roche Cobas Integra/ cobas 6000)
DZ568CL2	Enzymatic Homocysteine 2 Level Control Set (Roche Cobas Integra/ cobas 6000)
DZ568CON	Enzymatic Homocysteine 4 Level Control Set (Roche Cobas Integra/ cobas 6000)
DZ568RDG	Enzymatic Homocysteine Test Kit (Roche COBAS INTEGRA/ cobas c501/502 / c 311)
DZ178C-CAL	Myeloperoxidase (MPO) 5 Level Calibrator Set
DZ178C-CON	Myeloperoxidase (MPO) (3) Level Control Set
DZ178C-K	Myeloperoxidase (MPO) Assay
DZ688B-CON	25-OH Vitamin D EIA Control Kit
DZ688B-K	25-Hydroxy Vitamin D Assay Kit

# CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

CIVIL CODE § 1189

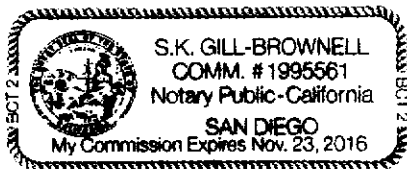
State of California

County of San Diego

On 14th June 2013 before me, S.K. Gill-Brownell Notary Public

personally appeared Ashley Driscoll

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.



I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature: S.K. Gill-Brownell  
Signature of Notary Public

Place Notary Seal Above

## OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

### Description of Attached Document

Title or Type of Document: EC Declaration of Conformity

Document Date: 14th June 2013 Number of Pages: one

Signer(s) Other Than Named Above: \_\_\_\_\_

### Capacity(ies) Claimed by Signer(s)

Signer's Name: \_\_\_\_\_ Signer's Name: \_\_\_\_\_

☐ Corporate Officer — Title(s): \_\_\_\_\_ ☐ Corporate Officer — Title(s): \_\_\_\_\_

☒ Individual

☐ Partner — ☐ Limited ☐ General

☐ Attorney in Fact

☐ Trustee

☐ Guardian or Conservator

☐ Other: \_\_\_\_\_

Signer Is Representing: \_\_\_\_\_

RIGHT THUMBPRINT  
OF SIGNER  
Top of thumb here

☐ Individual

☐ Partner — ☐ Limited ☐ General

☐ Attorney in Fact

☐ Trustee

☐ Guardian or Conservator

☐ Other: \_\_\_\_\_

Signer Is Representing: \_\_\_\_\_

RIGHT THUMBPRINT  
OF SIGNER  
Top of thumb here