

Certificate of CE-Registration

MDSS

Medical Device Safety Service

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Diazyme Laboratories
12889 Gregg Court
POWAY, CA. 92064

UNITED STATES OF AMERICA

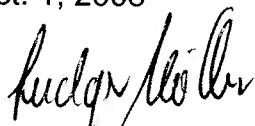
as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the *in vitro* diagnostic medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated Oct. 1, 2008

Medical Device Safety Service GmbH (MDSS) has furthermore given notification of the manufacturer's devices to concerned Member State Competent Authorities in accordance with article 10.6 of the *In Vitro* Diagnostic Medical Device Directive 98/79/EC.

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

Oct. 1, 2008



Ludger Möller
-President-
MDSS GmbH

Annex A: Oct. 1, 2008 Manufacturer: Diazyme Laboratories

Registration Number	Notified EDMS Description	EDMS Code	Risk Class	NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD	Countries Notified
DE/CA09/0170/IVD/1169A1	Homocysteine	12 13 01 09 00	Other	N/A	N/A	AU BG CY CZ DK EE FI FR DE GR HU IS IE IT LV LT LI LU MT NL NO PL SK SI SE CH UK **
Product Name						
Homocysteine Enzymatic Assay						
Homocysteine Microtiter Plate Assay						
Homocysteine Enzymatic Assay for Cobas Integra®						
Homocysteine Enzymatic 2 Reagent Assay						
DE/CA09/0170/IVD/1170A1	Lithium	11 03 01 06 00	Other	N/A	N/A	FR DE IT CH UK **
Product Name						
Lithium Enzymatic Assay						
Liquid Stabel Enzymatic Lithium Reagent Assay						
DE/CA09/0170/IVD/1183A1	Sodium	11 03 01 10 00	Other	N/A	N/A	FR DE IT CH UK **
Product Name						
Sodium Enzymatic Assay						
DE/CA09/0170/IVD/1184A1	Potassium	11 03 01 09 00	Other	N/A	N/A	FR DE IT CH UK **
Product Name						
Potassium Enzymatic Assay						
DE/CA09/0170/IVD/1301A1	Bile Acids	11 02 01 02 00	Other	N/A	N/A	BE DK FI FR DE IE IT LU NL NO PL SI CH UK **
Product Name						
Total Bile Acids Enzymatic Assay						
DE/CA09/0170/IVD/1491A1	Glycosylated/Glycated Haemoglobin (HbA1C)	11 02 01 14 00	Other	N/A	N/A	FR DE IT PL CH UK **
Product Name						
HbA1c Enzymatic Assay						
Direct Enzymatic HbA1c Assay						

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Annex A: Oct. 1, 2008 Manufacturer: Diazyme Laboratories

Registration Number	Notified EDMS Description	EDMS Code	Risk Class	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD	Countries Notified
DE/CA09/0170/IVD/1651A1	Other Enzymes	11 01 01 90 00	Other	N/A	N/A	FR DE IT CH UK **
Product Name Adenosine Deaminase Assay						
DE/CA09/0170/IVD/1652A1	Bicarbonate	11 03 01 02 00	Other	N/A	N/A	FR DE IT CH UK **
Product Name Carbon Dioxide Enzymatic Assay						
DE/CA09/0170/IVD/1653A1	Calibrators Single Component (CC)	11 50 03 02 00	Other	N/A	N/A	AU BG CY CZ DK EE FI FR DE GR HU IS IE IT LV LT LI LU MT NL NO PL SK SI SE CH UK **
Product Name Homocysteine Enzymatic Assay						
Homocysteine Enzymatic 2 Reagent Assay						
Lithium Enzymatic Assay						
Sodium Enzymatic Assay						
Potassium Enzymatic Assay						
Total Bile Acids Enzymatic Assay						
HbA1c Enzymatic Assay						
Direct Enzymatic HbA1c Assay						
Adenosine Deaminase Assay						
Carbon Dioxide Enzymatic Assay						
Creatinine Liquid Reagent Assay						
Fructosamine (Glycated Serum Protein) Enzymatic Assay						
HDL-Cholesterol Reagent						
LDL-Cholesterol Reagent						
Apolipoprotein A-1 Assay						
Apolipoprotein B Assay						
Cystatin C Assay						
Liquid Stabel Enzymatic Lithium Reagent Assay						



Annex A: Oct. 1, 2008 Manufacturer: Diazyme Laboratories

Registration Number	Notified EDMS Description	EDMS Code	Risk Class	NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD	Countries Notified
DE/CA09/0170/IVD/1665A1	Other Specific Control Sera (CC)	11 50 02 90 00	Other	N/A		AU BG CY CZ DK EE FI FR DE GR HU IS IE IT LV LT LI LU MT NL NO PL SK SI SE CH UK **
Product Name						
Homocysteine Enzymatic Assay						
Homocysteine Enzymatic 2 Reagent Assay						
Lithium Enzymatic Assay						
Sodium Enzymatic Assay						
Potassium Enzymatic Assay						
Total Bile Acids Enzymatic Assay						
HbA1c Enzymatic Assay						
Direct Enzymatic HbA1c Assay						
Adenosine Deaminase Assay						
Carbon Dioxide Enzymatic Assay						
Creatinine Liquid Reagent Assay						
Fructosamine (Glycated Serum Protein) Enzymatic Assay						
HDL-Cholesterol Reagent						
LDL-Cholesterol Reagent						
Apolipoprotein A-1 Assay						
Apolipoprotein B Assay						
Cystatin C Assay						
Liquid Stabel Enzymatic Lithium Reagent Assay						
DE/CA09/0170/IVD/1808A1	Creatinine	11 02 01 07 00	Other	N/A	N/A	FR DE IT CH UK **
Product Name						
Creatinine Liquid Reagent Assay						
DE/CA09/0170/IVD/2214	Fructosamine	11 02 01 10 00	Other	N/A	N/A	DE PL
Product Name						
Fructosamine (Glycated Serum Protein) Enzymatic Assay						
DE/CA09/0170/IVD/2215	High Density Lipoprotein Cholesterol	11 02 01 15 00	Other	N/A	N/A	DE PL
Product Name						
HDL-Cholesterol Reagent						

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Annex A: Oct. 1, 2008 Manufacturer: Diazyme Laboratories

Registration Number	Notified EDMS Description	EDMS Code	Risk Class	NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD	Countries Notified
DE/CA09/0170/IVD/2216	Low Density Lipoprotein Cholesterol	11 02 01 21 00	Other	N/A	N/A	DE PL
<u>Product Name</u> LDL-Cholesterol Reagent						
DE/CA09/0170/IVD/2217	Apolipoprotein A I	12 01 04 01 00	Other	N/A	N/A	DE
<u>Product Name</u> Apolipoprotein A-1 Assay						
DE/CA09/0170/IVD/2218	Apolipoprotein B	12 01 04 03 00	Other	N/A	N/A	DE
<u>Product Name</u> Apolipoprotein B Assay						
DE/CA09/0170/IVD/2219	Other Other Plasma Proteins	12 01 90 90 00	Other	N/A	N/A	DE
<u>Product Name</u> Cystatin C Assay						

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Medical Device Safety Service



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30.09.20082008-10-01

Confirmation IVD Notification, IVDD 98/79/EC, article 10.6

Dear Dr. Datta

As requested and in accordance with Article 10.6 of the IVDD 98/79/EC, MDSS has forwarded the following IVD notifications to the Competent Authority of Poland.

EDMS Code	Risk Class	EDMS Description
11 02 01 14 00	"Other"	Glycosylated/Glycated Haemoglobin (HbA1C)
11 02 01 10 00	"Other"	Fructosamine
11 02 01 15 00	"Other"	High Density Lipoprotein Cholesterol
11 02 01 21 00	"Other"	Low Density Lipoprotein Cholesterol

Registration / Notification is therefore in accordance with EU legislation. We remind you that all products must meet the applicable provision of the European and national regulation before they may be placed on the market.

Enclosed is an updated MDSS Certificate of Registration summarizing the notifications performed by MDSS on behalf of Diazyme Laboratories as of today.

We wish you a successful product launch in Europe.

Best regards,

Joy Grimm
Medical Device Safety Service GmbH

