

Certificate of CE-Registration

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:

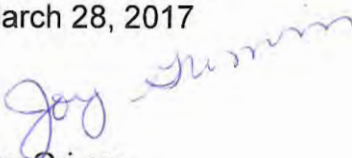
**Diazyme Laboratories
12889 Gregg Court
92064 Poway, CA
UNITED STATES OF AMERICA**

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated March 28, 2017

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.

March 28, 2017


Joy Grimm
Senior Consultant - IVD
MDSS GmbH

REF	Notified Device Names	EDMA Code	EDMA Description	Class	EC Certificate No. & Expiry	German Registration Number
DZ042A-CAL	Total Bile Acids Calibrators	11 50 03 02 00	Calibrators Single Component (CC)	"Other"	N/A	DE/CA09/0170/D10/IVD/032-03
DZ072B-CAL	Creatinine Liquid Reagents Assay Calibrators	"	"	"	"	"
DZ112B-CAL	Glycated Serum Proteins Enzymatic Assay Calibrators	"	"	"	"	"
DZ113C-CAL	Liquid Stable Potassium Enzymatic Calibrators	"	"	"	"	"
DZ114B-CAL	Liquid Stable Enzymatic Sodium Calibrators	"	"	"	"	"
DZ116A-CAL	Lithium Enzymatic Calibrators	"	"	"	"	"
DZ116B-CA5	Lithium Five Point Calibrator	"	"	"	"	"
DZ116B-CAL	Liquid Stable Enzymatic Lithium Calibrators	"	"	"	"	"
DZ117A-CAL	Adenosine Deaminase Enzymatic Assay Calibrators	"	"	"	"	"
DZ122A-CAL	Carbon Dioxide Enzymatic Assay Calibrators	"	"	"	"	"
DZ123A-CAL	5' Nucleotidase Calibrator	"	"	"	"	"
DZ130A-CAL	HDL-LDL Calibrators	"	"	"	"	"
DZ131A-CAL, DZ131B-CAL	Lipoprotein (a) Calibrators	"	"	"	"	"
DZ132A-CAL	Lipase Calibrator	"	"	"	"	"
DZ133C-CAL	Cystatin C Calibrators	"	"	"	"	"
DZ135A-CAL	High Sensitivity C-Reactive Proteins (hsCRP) Calibrators	"	"	"	"	"
DZ136A-CAL	Albumin Calibrator Set	"	"	"	"	"
DZ141A-CAL	Apolipoprotein A-1 Calibrators	"	"	"	"	"
DZ141A-CAL	Apolipoprotein B Calibrators	"	"	"	"	"
DZ145A-CAL	Cardiac Troponin I Assay Calibrator	"	"	"	"	"
DZ150A-CAL	Bilirubin Calibrator	"	"	"	"	"
DZ168A-CAL	Direct Enzymatic HbA1c Calibrators	"	"	"	"	"
DZ168C-CAL	Diazyme Direct HbA1c Assay Calibrator Set	"	"	"	"	"
DZ178C-CAL	Myeloperoxidase Calibrator Set	"	"	"	"	"
DZ179A-CAL	D-Dimer Calibrator	"	"	"	"	"
DZ187A-CAL	Retinol Binding Protein Calibrator Set	"	"	"	"	"
DZ526A-CAL	Ferritin Calibrator Set	"	"	"	"	"
DZ558A-CAL	Procalcitonin Calibrator Set	"	"	"	"	"
DZ568A-CA5	Homocysteine Enzymatic Assay 5 Point Calibrator Set	"	"	"	"	"
DZ568A-CAL, DZ568B-CAL	Homocysteine Enzymatic Assay Calibrator	"	"	"	"	"
DZ568CAL	Homocysteine Partner Channel Calibrator	"	"	"	"	"
DZ688A-CAL	25-Hydroxy Vitamin D Calibrators	"	"	"	"	"
DZ688B-CAL	25-OH Vitamin D EIA Assay Calibrator	"	"	"	"	"
DZ688C-CAL	25-Hydroxy Vitamin D Calibrator Set	"	"	"	"	"



REF	Notified Device Names	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry	German Registration Number
DZ689A-CAL	Diazyme Vitamin B12 Calibrator Set	"	"	"	"	"
DZ785A-CAL	Diazyme Heart-type Fatty Acid Binding Protein (H-FABP) Calibrator Set	"	"	"	"	"
DZ863A-CAL	Carcinoembryonic Calibrator Set	"	"	"	"	"
DZ865A-CAL	Insulin Calibrator Set	"	"	"	"	"
DZ869A-CAL	Alpha Fetoprotein Calibrator Set	"	"	"	"	"
DZ169A-CAL	Diazyme Human Kappa/Lambda Free Light Chain Calibrator Set	"	"	"	"	"
DZ062A-CAL	N-Acetyl-β-Glucosaminidase Calibrators	11 50 03 90 00	Other Calibrators and Standards (Clinical Chemistry)	"Other"	N/A	DE/CA09/0170/D10/IVD/013-01
DZ082B-CAL	α-L-Fucosidase Calibrator	"	"	"	"	"
DZ147A-CAL	Myoglobin Calibrators	"	"	"	"	"
DZ690A-CAL	Diazyme Folate Assay Calibrator Set	"	"	"	"	"
DZ042A-CON	Total Bile Acids Control	11 50 02 90 00	Other Specific Control Sera (CC)	"Other"	N/A	DE/CA09/0170/D10/IVD/031-04
DZ072B-CON	Creatinine Controls	"	"	"	"	"
DZ112B-CON	Glycated Serum Proteins Enzymatic Assay Controls	"	"	"	"	"
DZ113C-CON	Liquid Stable Enzymatic Potassium Controls	"	"	"	"	"
DZ114B-CON	Liquid Stable Enzymatic Sodium Controls	"	"	"	"	"
DZ116A-CON	Lithium Enzymatic Controls	"	"	"	"	"
DZ116B-CON	Liquid Stable Enzymatic Lithium Controls	"	"	"	"	"
DZ117A-CON	Adenosine Deaminase Enzymatic Assay Controls	"	"	"	"	"
DZ122A-CON	Carbon Dioxide Enzymatic Assay Controls	"	"	"	"	"
DZ123A-CON	5' Nucleotidase Control	"	"	"	"	"
DZ131A-CON,	Lipoprotein (a) Controls	"	"	"	"	"
DZ131B-CON						
DZ132A-CON	Lipase Controls	"	"	"	"	"
DZ133C-CON	Cystatin C Assay Controls	"	"	"	"	"
DZ133D-CON	Cystatin C POC Test Controls	"	"	"	"	"
DZ135A-CON	hs-CRP Controls	"	"	"	"	"
DZ135B-CON	hsCRP POC Test Controls	"	"	"	"	"
DZ136A-CON	Albumin Control Set	"	"	"	"	"
DZ145A-CON	Cardiac Troponin I Assay Controls	"	"	"	"	"
DZ147A-CON	Myoglobin Controls	"	"	"	"	"
DZ168A-CON	Direct Enzymatic HbA1c Controls	"	"	"	"	"
DZ168B-CON	SMART HbA1c Controls	"	"	"	"	"
DZ168C-CON	Diazyme Direct HbA1c Assay Control Set	"	"	"	"	"
DZ178C-CON	Myeloperoxidase Control Set	"	"	"	"	"
DZ179A-CON	D-Dimer Controls	"	"	"	"	"



REF	Notified Device Names	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry	German Registration Number
DZ187A-CON	Retinol Binding Protein Control Set	"	"	"	"	"
DZ526A-CON	Ferritin Control Set	"	"	"	"	"
DZ558A	Procalcitonin Control Set	"	"	"	"	"
DZ558B-CON	Diazyme Procalcitonin POCT Control Set	"	"	"	"	"
DZ568A-CON	Homocysteine Enzymatic Assay Controls	"	"	"	"	"
DZ568B-CON	Homocysteine 2 level Controls	"	"	"	"	"
DZ568CL2	Homocysteine Partner Channel 2 Level Control Set	"	"	"	"	"
DZ568CON	Homocysteine Partner Channel 4 Level Control Set	"	"	"	"	"
DZ688A-CON	25-Hydroxy Vitamin D Controls	"	"	"	"	"
DZ688B-CON	25-Hydroxy Vitamin D EIA Assay Controls	"	"	"	"	"
DZ688C-CON	25-Hydroxy Vitamin D Control Set	"	"	"	"	"
DZ689A-CON	Diazyme Vitamin B12 Control Set	"	"	"	"	"
DZ690A-CON	Diazyme Folate Assay Control Set	"	"	"	"	"
DZ785A-CON	Diazyme Heart-type Fatty Acid Binding Protein (H-FABP) Control Set	"	"	"	"	"
DZ863A-CON	Carcinoembryonic Antigen Control Set	"	"	"	"	"
DZ865A-CON	Insulin Control Set	"	"	"	"	"
DZ869A-CON	Alpha Fetoprotein Control Set	"	"	"	"	"
DZ169A-CON	Diazyme Human Kappa/Lambda Free Light Chain Control Set	"	"	"	"	"
DZ062A-CON	N-Acetyl-β-Glucosaminidase Controls	11 50 02 01 00	Enzyme Control Sera	"Other"	N/A	DE/CA09/0170/D10/IVD/011-01
DZ082B-CON	α-L-Fucosidase Control	"	"	"	"	"
DZ150A-CON	Bilirubin Controls	11 50 02 03 00	Bilirubin Control Sera	"Other"	N/A	DE/CA09/0170/D10/IVD/016
DZ138A-CON	Multi-Analyte Lipid Control Set	11 50 02 02 00	Lipid Control Sera	"Other"	N/A	DE/CA09/0170/D10/IVD/009
DZ082B	α-L-Fucosidase Assay	11 01 01 90 00	Other Enzymes	"Other"	N/A	DE/CA09/0170/D10/VD/033-01
DZ117A	Adenosine Deaminase Assay	"	"	"	"	"
DZ062A	N-Acetyl-β-Glucosaminidase Assay	11 01 01 26 00	N-acetyl-β,D-Glucosaminidase	"Other"	N/A	DE/CA09/0170/D10/IVD/010
DZ147A	Myoglobin Assay	12 13 01 05 00	Myoglobin	"Other"	N/A	DE/CA09/0170/D10/IVD/014
DZ132A	Lipase Assay	11 01 01 23 00	Lipase	"Other"	N/A	DE/CA09/0170/D10/IVD/020-01
DZ123A	5'-Nucleotidase Assay	11 01 01 01 00	5'-Nucleotidase	"Other"	N/A	DE/CA09/0170/D10/IVD/019
DZ133C	Cystatin C Assay	12 01 90 90 00	Other Other Plasma Proteins	"Other"	N/A	DE/CA09/0170/D10/IVD/024-01
DZ133D-SMA	Cystatin C POC Test Kit	"	"	"	"	"



REF	Notified Device Names	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry	German Registration Number
DZ688A	25-OH Vitamin D Assay	12 06 03 10 00	25-Hydroxyvitamin D3	"Other"	N/A	DE/CA09/0170/D10/IVD/021-01
DZ688B	25-OH Vitamin D EIA Assay	"	"	"	"	"
DZ688C	25-Hydroxy Vitamin D Assay	"	"	"	"	"
DZ145A	Cardiac Troponin I Assay	12 13 01 07 00	Troponin (T + I)	"Other"	N/A	DE/CA09/0170/D10/IVD/018
DZ135A	hs-CRP Assay	12 13 01 10	High Sensitivity C-Reactive Protein	"Other"	N/A	DE/CA09/0170/D10/IVD/022-01
DZ135B-SMA	hsCRP POC Test Kit					
DZ150A	Total Bilirubin Assay	11 02 01 03 00	Bilirubin	"Other"	N/A	DE/CA09/0170/D10/IVD/017
DZ151A	Direct Bilirubin Assay					
DZ179A	D-Dimer Assay	13 02 05 03 00	D-Dimer	"Other"	N/A	DE/CA09/0170/D10/IVD/015
DZ568A, DZ568AK06, DZ568K07, DZ568RDG, DZ568B	Homocysteine Enzymatic Assay	12 13 01 09 00	Homocysteine	"Other"	N/A	DE/CA09/0170D10//IVD/037-01
DZ568B	Homocysteine Enzymatic 2 Reagent Assay	"	"	"	"	"
DZ568B-SMA	Homocysteine POC Test Kit	"	"	"	"	"
DZ178C	Myeloperoxidase Immunoassay	12 13 01 12	Myeloperoxidase	"Other"	N/A	DE/CA09/0170/D10/IVD/023-01
DZ136A	Albumin Assay	11 02 01 01 00	Albumin (CC)	"Other"	N/A	DE/CA09/0170/D10/IVD/012
DZ116B	Liquid Stable Enzymatic Lithium Reagent Assay	11 03 01 06 00	Lithium	"Other"	N/A	DE/CA09/0170/D10/IVD/039-01
DZ114B	Liquid Stable Enzymatic Sodium Assay	11 03 01 10 00	Sodium	"Other"	N/A	DE/CA09/0170/D10/IVD/036-01
DZ113C	Liquid Stable Potassium Enzymatic Assay	11 03 01 09 00	Potassium	"Other"	N/A	DE/CA09/0170/D10/IVD/038-01
DZ168A	Direct Enzymatic HbA1c Assay	11 02 01 14 00	Glycosylated/Glycated Haemoglobin (HbA1C)	"Other"	N/A	DE/CA09/0170/D10/IVD/034-02
DZ168B, ST0110	SMART HbA1c Assay	"	"	"	"	"
DZ168C	Diazyme Direct HbA1c Assay (Enzymatic, On-Board Lysis)	"	"	"	"	"
DZ526A	Ferritin Assay	12 12 01 90 00	Other Liver Function (immunchemistry)	"Other"	N/A	DE/CA09/0170/D10/IVD/008
DZ187A	Retinol Binding Protein Assay	12 01 03 07 00	Retinol Binding Protein	"Other"	N/A	DE/CA09/0170/D10/IVD/007



REF	Notified Device Names	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry	German Registration Number
DZ558A	Procalcitonin Assay	12 06 90 16 00	Procalcitonin	"Other"	N/A	DE/CA09/0170/D10/IVD/006-01
DZ558A-SMA	Procalcitonin POC Test Kit	"	"	"	"	"
DZ558A-CUBE	Diazyme CUBE Procalcitonin POCT Kit	"	"	"	"	"
DZ869A	Alpha-Fetoprotein Assay	12 03 90 01 00	Alphafetoprotein	"Other"	N/A	DE/CA09/0170/IVD/D10/005
DZ865A	Insulin Assay	12 06 01 03 00	Insulin	"Other"	N/A	DE/CA09/0170/D10/IVD/004
DZ112B	Glycated Serum Protein Assay	11 02 01 10 00	Fructosamine	"Other"	N/A	DE/CA09/0170/D10/IVD/029-01
DZ112B-SMA	Glycated Serum Protein POC Test Kit	"	"	"	"	"
DZ863A	Carcinoembryonic Antigen Assay	12 03 01 31 00	Carcinoembryonic Antigen	"Other"	N/A	DE/CA09/0170/D10/IVD/003
DZ785A	Diazyme Heart-type Fatty Acid Binding Protein (H-FABP) Assay	12 13 01 03	Heart-Type Fatty Acid-Binding Protein	"Other"	N/A	DE/CA09/0170/D10/IVD/002
DZ689A-K	Diazyme Vitamin B12 Assay	12 07 02 04 00	Diazyme Vitamin B12 Assay	"Other"	N/A	DE/CA09/0170/D10/IVD/001
DZ690A	Diazyme Folate Assay Kit	12 07 01 03 00	Folate	"Other"	N/A	DE/CA09/0170/D10/IVD/041
DZ122A	Carbon Dioxide Enzymatic Assay	11 03 01 02 00	Bicarbonate	"Other"	N/A	
DZ072B	Creatinine Liquid Reagent Assay	11 02 01 07 00	Creatinine	"Other"	N/A	DE/CA09/0170/D10/IVD/030-02
DZ042A	Total Bile Acids Enzymatic Assay	11 02 01 02 00	Bile Acids	"Other"	N/A	DE/CA09/0170/D10/IVD/035-01
DZ129A	HDL-Cholesterol Assay	11 02 01 15 00	High Density Lipoprotein Cholesterol	"Other"	N/A	DE/CA09/0170/D10/IVD/028-01
DZ128A	LDL-Cholesterol Assay	11 02 01 21 00	Low Density Lipoprotein Cholesterol	"Other"	N/A	DE/CA09/0170/D10/IVD/027-01
DZ131A	Lipoprotein (a) Assay	12 01 04 01 00	Apolipoprotein A I	"Other"	N/A	DE/CA09/0170/D10/IVD/026-01
DZ141A	Apolipoprotein A-1 Assay	"	"	"	"	"
DZ142A	Apolipoprotein B Assay	12 01 04 03 00	Apolipoprotein B	"Other"	N/A	DE/CA09/0170/D10/IVD/025-01
DZ169A	Diazyme Human Kappa Free Light Chain Assay	12 01 01 20 00	Kappa and Lambda Chain	"Other"	N/A	DE/CA09/0170/D10/IVD/042
DZ170A	Diazyme Human Lambda Free Light Chain Assay	"	"	"	"	"

