

Certificate of CE-Registration



mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG bzw. 98/79/EG) für den Hersteller

Firststep Bioresearch Inc .
3F, No2. Lane 31, Sec. 1,
Huan-Dung Rd. Hsin-Shi,
Tainan 74146
Taiwan

as stipulated and demanded by the aforementioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

See attached product list

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

May 2010

Werner Sander •
President & CEO

Šiuo patvirtinama, kad sutinkamai su medicinos direktyva 93/42EEB arba direktyva 98/79EB mdi Europa GmbH sutinka prisiimti visą atsakomybę ir atlikti visas prievolės kaip

Firststep Bioresearch Inc.
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Taivanis

Įgaliotas atstovas kaip nustatyta ir reikalaujama aukščiau minėtose direktyvose. Vokietijos kompetetingos institucijossuteikė gamintojo medicinos prietaisams čiuos registracijos numerius.

Žr. pridedamą produktų sąrašą.

Gamintojas pateikė mdi Europa visus būtinus dokumentus kartu su atitinkama atitiktie deklaracija, patvirtinančia, kad medicinos prietaisai atitinka pagrindinius 93/42/EEB arba 98/79EB reikalavimus. Pareigūnas saugai Vokietijoje paskirtas pagal §31 MPG

2010 m. gegužė.

(parašas)

Werner Sander

Prezidentas ir direktorius

Tikslus ir oficialus dokumento vertimas iš anglų kalbos.

Vertėjas pagal LR BK 293 str. įspėtas.

Vertė: J. Palumickienė

Data: 2013-01-10

UAB Diagnostinės Sistemos

Kalvarijų sodų 1-oji g. 2

LT-08342 Vilnius



Attachment to *Certificate of CE-Registration* of May 2010
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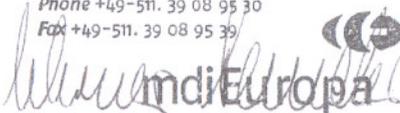
Drug Of Abuse Screen Test		Medical device (Description)	EDMA Code	Registration No.
Catalog No.	Item Description			
D001- C/ D	(AMP) Amphetamine, cassette/ dipstick	<i>Amphetamines Group - Rapid Test</i>	1270090100	DE/CA09/0760/622
D002- C/ D	(BAR) Barbiturates, cassette/ dipstick	<i>Barbiturates - Rapid Test</i>	1270090300	DE/CA09/0760/623
D003- C/ D	(BZD) Benzodiazepine, cassette/ dipstick	<i>Benzodiazepines - Rapid Test</i>	1270090400	DE/CA09/0760/624
D004- C/ D	(COC) Cocaine, cassette/ dipstick	<i>Cocaine + Cocaine Metabolites - Rapid Test</i>	1270090600	DE/CA09/0760/626
D005- C/ D	(MDMA) Ecstasy, cassette/ dipstick	<i>Other Drugs of Abuse/Toxicology Rapid Tests</i>	1270099000	DE/CA09/0760/631
D006- C/ D	(THC) Marijuana, cassette/ dipstick	<i>Cannabinoids - Rapid Test</i>	1270090500	DE/CA09/0760/625
D007- C/ D	(MTD) Methadone, cassette/ dipstick	<i>Methadone - Rapid Test</i>	1270090700	DE/CA09/0760/627
D008- C/ D	(MET) Methamphetamine, cassette/ dipstick	<i>Amphetamines Group - Rapid Test</i>	1270090100	DE/CA09/0760/622
D009- C/ D	(MOR) Morphine, cassette/ dipstick	<i>Opiates - Rapid Test</i>	1270090800	DE/CA09/0760/628
D010- C/ D	(OXY) Oxycodone, cassette/ dipstick	<i>Other Drugs of Abuse/Toxicology Rapid Tests</i>	1270099000	DE/CA09/0760/631
D011- C/ D	(PCP) Phencyclidine, cassette/ dipstick	<i>Phencyclidine - Rapid Test</i>	1270090900	DE/CA09/0760/629
D012- C/ D	(TCA) Tricyclic Antidepressants, cassette/ dipstick	<i>Tricyclic Antidepressants - Rapid Test</i>	1270091000	DE/CA09/0760/630
D013- C/ D	(BUP) Buprenorphine, cassette/ dipstick	<i>Other Drugs of Abuse/Toxicology Rapid Tests</i>	1270099000	DE/CA09/0760/631
D014- C/ D	(KET) Ketamine, cassette/ dipstick	<i>Other Drugs of Abuse/Toxicology Rapid Tests</i>	1270099000	DE/CA09/0760/631

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D015- C/ D	(TRD)Tramadol, cassette/ dipstick	<i>Other Drugs of Abuse/Toxicology Rapid Tests</i>	1270099000	DE/CA09/0760/631
D016- C/ D	(PPX)Propoxyphene, cassette/ dipstick	<i>Other Drugs of Abuse/Toxicology Rapid Tests</i>	1270099000	DE/CA09/0760/631
D200-C	any 2 parameters, cassette	<i>Multiple Drugs of Abuse/Toxicology Rapid Tests</i>	1270097000	DE/CA09/0760/646
D200-D	any 2 parameters, dipcard	<i>Multiple Drugs of Abuse/Toxicology Rapid Tests</i>	1270097000	DE/CA09/0760/646
D300-D	any 3 parameters, dipcard	<i>Multiple Drugs of Abuse/Toxicology Rapid Tests</i>	1270097000	DE/CA09/0760/646
D400-D	any 4 parameters, dipcard	<i>Multiple Drugs of Abuse/Toxicology Rapid Tests</i>	1270097000	DE/CA09/0760/646
D500-D	any 5 parameters, dipcard	<i>Multiple Drugs of Abuse/Toxicology Rapid Tests</i>	1270097000	DE/CA09/0760/646
D600-D	any 6 parameters, dipcard	<i>Multiple Drugs of Abuse/Toxicology Rapid Tests</i>	1270097000	DE/CA09/0760/646
D700-D	any 7 parameters, dipcard	<i>Multiple Drugs of Abuse/Toxicology Rapid Tests</i>	1270097000	DE/CA09/0760/646

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THE MEDICAL DEVICE SERVICE-MANAGEMENT

Attachment to Certificate of CE-Registration of May 2010
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Myocardial Marker One-StepTest		Medical device (Description)	EDMA Code	Registration No.
Catalog No.	Item Description			
M010-C	(Tnl) Troponin-I, serum, cassette	<i>Troponin I/T - Rapid Test</i>	1270130300	DE/CA09/0760/659
M011-C	(Tnl) Troponin-I, whole blood, cassette	<i>Troponin I/T - Rapid Test</i>	1270130300	DE/CA09/0760/659
M020-C	(CRP) C-Reactive Protein, serum, cassette	<i>C-Reactive Protein - Rapid Test</i>	1270110100	DE/CA09/0760/657
M021-C	(CRP) C-Reactive Protein, whole blood, serum, cassette	<i>C-Reactive Protein - Rapid Test</i>	1270110100	DE/CA09/0760/657
M030-C	(MYO) Myoglobin, serum, cassette	<i>Myoglobin - Rapid Test</i>	1270130200	DE/CA09/0760/660
M040-C	(CK-MB), serum, cassette	<i>CK - MB / Myoglobin - Rapid Test</i>	1270130100	DE/CA09/0760/661
M050-C	(FABP) Fatty Acid Binding Protein, serum, cassette	<i>Other Cardiac Marker Rapid Tests</i>	1270139000	DE/CA09/0760/658
M051-C	(FABP) Fatty Acid Binding Protein, whole blood, cassette	<i>Other Cardiac Marker Rapid Tests</i>	1270139000	DE/CA09/0760/658
M200-C	(FABP + Tnl), serum, cassette	<i>Other Cardiac Marker Rapid Tests</i>	1270139000	DE/CA09/0760/658
M201-C	(FABP + Tnl), whole blood, cassette	<i>Other Cardiac Marker Rapid Tests</i>	1270139000	DE/CA09/0760/658
M300-C	(CK-MB+MYO+Tnl), serum, cassette	<i>Other Cardiac Marker Rapid Tests</i>	1270139000	DE/CA09/0760/658
M301-C	(CK-MB+MYO+Tnl), whole blood, cassette	<i>Other Cardiac Marker Rapid Tests</i>	1270139000	DE/CA09/0760/658

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Tumor Marker One-Step Test		Medical device (Description)	EDMA Code	Registration No.
Catalog No.	Item Description			
C010-C/ D	(AFP)Alpha Feto-Protein, serum, cassette/ dipstick	Other Tumor Marker Rapid Tests	1270039000	DE/CA09/0760/645
C020-C/ D	(CEA) Carcinoma Embryonic Antigen, serum, cassette/ dipstick	Other Tumor Marker Rapid Tests	1270039000	DE/CA09/0760/645
C040-C	(FOB) Fecal Occult Blood, cassette	Other Tumor Marker Rapid Tests	1270039000	DE/CA09/0760/645

Pathogen Detection One-Step Test		Medical device (Description)	EDMA Code	Registration No.
Catalog No.	Item Description			
P020-C	(DNG) Dengue IgG/IgM, blood/serum, cassette	Other Other Virology Rapid Tests	1570909000	DE/CA09/0760/656
P030-C	(HPY) H. Pylori antibody, serum, cassette	H. Pylori - Rapid Test	1570010200	DE/CA09/0760/655
P031-C	(HPY) H. Pylori antigen, feces, cassette	H. Pylori - Rapid Test	1570010200	DE/CA09/0760/655
P040-C	(MAL)Malaria all subtypes, whole blood, cassette	Other Other Infectious Immunology Reagents	1590909000	DE/CA09/0760/654
P041-C	(MAL) Malaria P.F. subtype, whole blood, cassette	Other Other Infectious Immunology Reagents	1590909000	DE/CA09/0760/654
P050-C	(SYP) Syphilis T.P. antibody, serum, cassette	Syphilis - Rapid Test	1570010500	DE/CA09/0760/653
P260-C	Fecal Rotavirus and Adenovirus Duo Antigen Cassette	Other Other Virology Rapid Tests	1570909000	DE/CA09/0760/656
P061-C	Fecal Adenovirus Antigen, cassette	Other Other Virology Rapid Tests	1570909000	DE/CA09/0760/656
P062-C	Fecal Rotavirus Antigen, cassette	Other Other Virology Rapid Tests	1570909000	DE/CA09/0760/656