

Ministero della Salute

DGDMF

0056535-P-23/11/2015

I.5.1.e.2/2015/181



Imposta di
bollo assolta

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI
E DEL SERVIZIO FARMACEUTICO
UFF.04 EX DGFDM – DIAGNOSTICI IN VITRO

DGDMF.04/I.5.1.e.2/2015/181

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.lgs. n. 332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza del 06/11/2015 presentata dalla ditta Chema Diagnostica di Marco Fiore con sede legale e sede operativa in via Campania 2/4 - 60030 Monsano (AN) Italia – C.F. FRIMRC59P10H5010 P.IVA 01064910423;
CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 07 Agosto 2012;
VISTI gli atti d'ufficio;

HAVING REGARD to 98/79/EC directive concerning the in vitro diagnostic medical devices;
HAVING REGARD to legislative Decree (D.lgs.)n. 332/2000 reporting the accomplishment of 98/79/EC Directive;
HAVING REGARD to the request dated 06/11/2015 submitted by the company Chema Diagnostica di Marco Fiore legal site and and operative site via Campania 2/4 - 60030 Monsano (AN) Italia – C.F. FRIMRC59P10H5010 P.IVA 01064910423;
WHEREAS this company paid the fees required by Ministerial Decree (D.M.) August 07, 2012;
HAVING REGARD to the official deeds;

SI ATTESTA

IT IS ATTESTED

Che la ditta Chema Diagnostica di Marco Fiore con sede legale e sede operativa in via Campania 2/4 - 60030 Monsano (AN) Italia – C.F. FRIMRC59P10H5010 P.IVA 01064910423 è il fabbricante e ha marcato CE, come dispositivo medico-diagnostico in vitro, secondo le procedure previste dalla direttiva 98/79/CE, i seguenti prodotti:

That the Company Chema Diagnostica di Marco Fiore legal site and operative site via in via Campania 2/4 - 60030 Monsano (AN) Italia - C.F. FRIMRC59P10H5010 P.IVA 01064910423 is the manufacturer and affixed CE marking as in vitro diagnostic medical device, according to the Directive 98/79/EC, to the following products:

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| ALBUMIN | BC 0100 CH | 2 x 50 ml |
| ALBUMIN | BC 0500 CH | 4 x 125 ml |
| ALBUMIN Reagent 1 | BC BA01 | 1-20 l |
| ALKALINE PHOSPHATASE FL DGKC | AL F080 CH | 4 x 20 ml |
| ALKALINE PHOSPHATASE FL DGKC | AL F245 CH | 12 x 20 ml |
| ALKALINE PHOSPHATASE FL DGKC | AL F400 CH | 8 x 50 ml |
| ALKALINE PHOSPHATASE FL DGKC | AL F600 CH | 5 x 120 ml |
| ALKALINE PHOSPHATASE FL DGKC | AL 100F CH | 5 x 200 ml |
| ALKALINE PHOSPHATASE FL DGKC Reagent 1 | AL BA01 | 1-20 l |
| ALKALINE PHOSPHATASE FL DGKC Reagent 2 | AL BB01 | 1-20 l |
| ALKALINE PHOSPHATASE FL IFCC | AF F080 CH | 4 x 20 ml |
| ALKALINE PHOSPHATASE FL IFCC | AF F245 CH | 12 x 20 ml |
| ALKALINE PHOSPHATASE FL IFCC | AF F400 CH | 8 x 50 ml |
| ALKALINE PHOSPHATASE FL IFCC | AF F600 CH | 5 x 120 ml |
| ALKALINE PHOSPHATASE FL IFCC Reagent 1 | AF BA01 | 1-20 l |
| ALKALINE PHOSPHATASE FL IFCC Reagent 2 | AF BB01 | 1-20 l |
| AMYLASE EPS FL | EA F080 CH | 4 x 20 ml |
| AMYLASE EPS FL | EA F245 CH | 12 x 20 ml |
| AMYLASE EPS FL Reagent 1 | EA BA01 | 1-20 l |
| AMYLASE EPS FL Reagent 2 | EA BB01 | 1-20 l |
| AMYLASE FL | AM F060 CH | 6 x 10 ml |
| AMYLASE FL | AM F120 CH | 12 x 10 ml |
| AMYLASE FL | AM F245 CH | 12 x 20 ml |
| AMYLASE FL Reagent 1 | AM BA01 | 1-20 l |
| BICARBONATE FL | BR F060 CH | 6 x 10 ml |
| BICARBONATE FL | BR F245 CH | 12 x 20 ml |
| BICARBONATE FL | BR F400 CH | 4 x 100 ml |
| BICARBONATE FL Reagent 1 | BR BA01 | 1-20 l |
| CALCIUM | CA 0305 CH | 6 x 50 ml |
| CALCIUM | CA 0505 CH | 4 x 125 ml |
| CALCIUM Reagent 1 | CA BA01 | 1-20 l |
| CALCIUM Reagent 2 | CA BB01 | 1-20 l |
| CALCIUM ASX | CA 0100 CH | 2 x 50 ml |
| CALCIUM ASX | CA 0500 CH | 4 x 125 ml |
| CALCIUM ASX Reagent 1 | CA BA02 | 1-20 l |
| CHLORIDE | CL 0100 CH | 2 x 50 ml |
| CHLORIDE | CL 0500 CH | 4 x 125 ml |
| CHLORIDE Reagent 1 | CL BA01 | 1-20 l |
| CHOLESTEROL FL | CT F100 CH | 2 x 50 ml |
| CHOLESTEROL FL | CT F400 CH | 4 x 100 ml |
| CHOLESTEROL FL | CT 100F CH | 4 x 250 ml |
| CHOLESTEROL FL Reagent 1 | CT BA01 | 1-20 l |
| CHOLINESTERASE DGKC FL | CH F096 CH | 4 x 24 ml |
| CHOLINESTERASE DGKC FL | CH F245 CH | 12 x 24 ml |
| CHOLINESTERASE DGKC FL Reagent 1 | CH BA01 | 1-20 l |
| CHOLINESTERASE DGKC FL Reagent 2 | CH BB01 | 1-20 l |
| CK-MB FL IFCC/DGKC | MB F060 CH | 6 x 10 ml |

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CK-MB FL IFCC/DGKC
 CK-MB FL IFCC/DGKC Reagent 1
 CK-MB FL IFCC/DGKC Reagent 2
 CK-NAC FL IFCC/DGKC
 CK-NAC FL IFCC/DGKC
 CK-NAC FL IFCC/DGKC
 CK-NAC FL IFCC/DGKC Reagent 1
 CK-NAC FL IFCC/DGKC Reagent 2
 COPPER
 COPPER Reagent 1
 COPPER Reagent 2
 CREATININE
 CREATININE
 CREATININE Reagent 1
 CREATININE Reagent 2
 CREATININE-E FL
 CREATININE-E FL
 CREATININE-E FL
 CREATININE-E FL Reagent 1
 CREATININE-E FL Reagent 2
 DIBUCAINE REAGENT
 DIRECT BILIRUBIN FL
 DIRECT BILIRUBIN FL
 DIRECT BILIRUBIN FL Reagent 1
 DIRECT BILIRUBIN FL Reagent 2
 GAMMA GT FL
 GAMMA GT FL
 GAMMA GT FL
 GAMMA GT FL
 GAMMA GT FL Reagent 1
 GAMMA GT FL Reagent 2
 GLUCOSE FL
 GLUCOSE FL
 GLUCOSE FL Reagent 1
 GLUCOSE UV FL
 GLUCOSE UV FL Reagent 1
 GLUCOSE UV FL Reagent 2
 GOT/AST FL IFCC
 GOT/AST FL IFCC
 GOT/AST FL IFCC
 GOT/AST FL IFCC
 GOT/AST FL IFCC
 GOT/AST FL IFCC Reagent 1
 GOT/AST FL IFCC Reagent 2
 GPT/ALT FL IFCC
 GPT/ALT FL IFCC
 GPT/ALT FL IFCC
 GPT/ALT FL IFCC
 GPT/ALT FL IFCC
 GPT/ALT FL IFCC Reagent 1
 GPT/ALT FL IFCC Reagent 2

MB F120 CH 12 x 10 ml
 MB BA01 1-20 l
 MB BB01 1-20 l
 CK F060 CH 6 x 10 ml
 CK F120 CH 12 x 10 ml
 CK F245 CH 12 x 20 ml
 CK BA01 1-20 l
 CK BB01 1-20 l
 CU 0100 CH 4 x 25 ml
 CU BA01 1-20 l
 CU BB01 1-20 l
 CR 0500 CH 4 x 125 ml
 CR 1000 CH 4 x 250 ml
 CR BA01 1-20 l
 CR BB01 1-20 l
 CE F125 CH 5 x 25 ml
 CE F375 CH 15 x 25 ml
 CE F600 CH 10 x 60 ml
 CE BA01 1-20 l
 CE BB01 1-20 l
 CH F080 CH 4 x 0.2 ml
 DD F125 CH 5 x 25 ml
 DD F500 CH 10 x 50 ml
 DD BA01 1-20 l
 DD BB01 1-20 l
 GT F080 CH 4 x 20 ml
 GT F245 CH 12 x 20 ml
 GT F400 CH 8 x 50 ml
 GT F600 CH 5 x 120 ml
 GT BA01 1-20 l
 GT BB01 1-20 l
 GL F400 CH 4 x 100 ml
 GL 100F CH 4 x 250 ml
 GL BA01 1-20 l
 GL F601 CH 5 x 120 ml
 GL BA02 1-20 l
 GL BB02 1-20 l
 GO F080 CH 4 x 20 ml
 GO F245 CH 12 x 20 ml
 GO F400 CH 8 x 50 ml
 GO F600 CH 5 x 120 ml
 GO 100F CH 5 x 200 ml
 GO BA01 1-20 l
 GO BB01 1-20 l
 GP F080 CH 4 x 20 ml
 GP F245 CH 12 x 20 ml
 GP F400 CH 8 x 50 ml
 GP F600 CH 5 x 120 ml
 GP 100F CH 5 x 200 ml
 GP BA01 1-20 l
 GP BB01 1-20 l

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| HDL PRECIPITATING REAGENT | CD 0400 CH | 4 x 100 ml |
| HDL PRECIPITATING REAGENT Reagent 1 | CD BA01 | 1-20 l |
| HDL-direct FL | HD F080 CH | 4 x 20 ml |
| HDL-direct FL | HD F245 CH | 12 x 20 ml |
| HDL-direct FL | HD F400 CH | 4 x 100 ml |
| HDL-direct FL Reagent 1 | HD BA01 | 1-20 l |
| HDL-direct FL Reagent 2 | HD BB01 | 1-20 l |
| IRON CRX | FE 0100 CH | 2 x 50 ml |
| IRON CRX | FE 0500 CH | 4 x 125 ml |
| IRON CRX Reagent 1 | FE BA01 | 1-20 l |
| IRON FZ | FE F245 CH | 12 x 20 ml |
| IRON FZ | FE F400 CH | 8 x 50 ml |
| IRON FZ Reagent 1 | FE BA02 | 1-20 l |
| IRON FZ Reagent 2A | FE BB02 | 1-20 l |
| LDH FL DGKC | LD F060 CH | 6 x 10 ml |
| LDH FL DGKC | LD F120 CH | 12 x 10 ml |
| LDH FL DGKC | LD F245 CH | 12 x 20 ml |
| LDH FL DGKC Reagent 1 | LD BA01 | 1-20 l |
| LDH FL DGKC Reagent 2 | LD BB01 | 1-20 l |
| LDL-direct FL | DL F080 CH | 4 x 20 ml |
| LDL-direct FL Reagent 1 | DL BA01 | 1-20 l |
| LDL-direct FL Reagent 2 | DL BB01 | 1-20 l |
| LIPASE FL | LP F060 CH | 6 x 10 ml |
| LIPASE FL | LP F125 CH | 5 x 25 ml |
| LIPASE FL Reagent 1 | LP BA01 | 1-20 l |
| LIPASE FL Reagent 2 | LP BB01 | 1-20 l |
| MAGNESIUM | MG 0200 CH | 10 x 20 ml |
| MAGNESIUM | MG 0500 CH | 4 x 125 ml |
| MAGNESIUM Reagent 1 | MG BA01 | 1-20 l |
| MAGNESIUM Reagent 2 | MG BB01 | 1-20 l |
| MAGNESIUM XL | MX 0300 CH | 6 x 50 ml |
| MAGNESIUM XL | MX 0500 CH | 4 x 125 ml |
| MAGNESIUM XL Reagent 1 | MX BA01 | 1-20 l |
| PANCREATIC ISOAMYLASE EPS FL | PA F080 CH | 5 x 16 ml |
| PANCREATIC ISOAMYLASE EPS FL | PA F245 CH | 15 x 16 ml |
| PANCREATIC ISOAMYLASE EPS FL Reagent 1 | PA BA01 | 1-20 l |
| PANCREATIC ISOAMYLASE EPS FL Reagent 2 | PA BB01 | 1-20 l |
| PHOSPHORUS UV | PH 0100 CH | 2 x 50 ml |
| PHOSPHORUS UV | PH 0500 CH | 4 x 125 ml |
| PHOSPHORUS UV Reagent 1 | PH BA01 | 1-20 l |
| PROTEINS (TOTAL) | TP 0100 CH | 2 x 50 ml |
| PROTEINS (TOTAL) | TP 0500 CH | 4 x 125 ml |
| PROTEINS (TOTAL) | TP 1000 CH | 4 x 250 ml |
| PROTEINS (TOTAL) Reagent 1 | TP BA01 | 1-20 l |
| PROTEINS HS | HS 0100 CH | 2 x 50 ml |
| PROTEINS HS | HS 0500 CH | 4 x 125 ml |
| PROTEINS HS Reagent 1 | HS BA01 | 1-20 l |
| TOTAL BILIRUBIN FL | DT F125 CH | 5 x 25 ml |
| TOTAL BILIRUBIN FL | DT F500 CH | 10 x 50 ml |
| TOTAL BILIRUBIN FL Reagent 1 | DT BA01 | 1-20 l |
| TOTAL BILIRUBIN FL Reagent 2 | DT BB01 | 1-20 l |

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| TRIGLYCERIDES FL | TR F100 CH | 2 x 50 ml |
| TRIGLYCERIDES FL | TR F400 CH | 4 x 100 ml |
| TRIGLYCERIDES FL | TR 100F CH | 4 x 250 ml |
| TRIGLYCERIDES FL Reagent 1 | TR BA01 | 1-20 l |
| UREA COLOR FL | UC 100F CH | 4 x 250 ml |
| UREA COLOR FL | UC F400 CH | 4 x 100 ml |
| UREA UV FL | AZ F080 CH | 4 x 20 ml |
| UREA UV FL | AZ F245 CH | 12 x 20 ml |
| UREA UV FL | AZ F400 CH | 8 x 50 ml |
| UREA UV FL | AZ F600 CH | 5 x 120 ml |
| UREA UV FL | AZ 100F CH | 5 x 200 ml |
| UREA UV FL Reagent 1 | AZ BA01 | 1-20 l |
| UREA UV FL Reagent 2 | AZ BB01 | 1-20 l |
| URIC ACID AOX FL | AX F100 CH | 5 x 20 ml |
| URIC ACID AOX FL | AX F250 CH | 5 x 50 ml |
| URIC ACID AOX FL | AX F600 CH | 5 x 120 ml |
| URIC ACID AOX FL Reagent 1 | AX BA01 | 1-20 l |
| URIC ACID AOX FL Reagent 2 | AX BB01 | 1-20 l |
| URIC ACID T FL | AU F402 CH | 4 x 100 ml |
| URIC ACID T FL | AU F100 CH | 5 x 20 ml |
| URIC ACID T FL | AU F250 CH | 5 x 50 ml |
| URIC ACID T FL Reagent 1 | AU BA01 | 1-20 l |
| URIC ACID T FL Reagent 2 | AU BB01 | 1-20 l |
| ZINC | ZN 0125 CH | 5 x 25 ml |
| ZINC Reagent 1 | ZN BA01 | 1-20 l |
| ZINC Reagent 2 | ZN BB01 | 1-20 l |
| AUTOCAL H | AT 0015 CH | 5 x 3 ml |
| AUTOCAL H | AT 0030 CH | 10 x 3 ml |
| QUANTINORM CHEMA | QN 0025 CH | 5 x 5 ml |
| QUANTINORM CHEMA | QN 0050 CH | 10 x 5 ml |
| QUANTIPATH CHEMA | QP 0025 CH | 5 x 5 ml |
| QUANTIPATH CHEMA | QP 0050 CH | 10 x 5 ml |
| REFERENCE P MULTICALIBRATOR | CP 0005 CH | 5 x 1 ml |
| CRP CALIBRATOR | RP CA05 CH | 5 x 1 ml |
| CRP FL | RP 0090 CH | 1 x 90 ml |
| CRP FL Reagent 1 | RP BA01 | 1-20 l |
| CRP FL Reagent 2 | RP BB01 | 1-20 l |
| IgA FL | GA 0050 CH | 1 x 50 ml |
| IgA FL | GA 0100 CH | 2 x 50 ml |
| IgG FL | GG 0050 CH | 1 x 50 ml |
| IgG FL | GG 0100 CH | 2 x 50 ml |
| IgM FL | GM 0050 CH | 1 x 50 ml |
| IgM FL | GM 0100 CH | 2 x 50 ml |
| IgM FL Reagent 1 | GM BA01 | 1-20 l |
| IgM FL Reagent 2 | GM BB01 | 1-20 l |
| TRASFERRIN FL | TF 0050 CH | 1 x 50 ml |
| TRASFERRIN FL | TF 0100 CH | 2 x 50 ml |

I suddetti prodotti, in base all'art. 4 della direttiva 98/79/CE, sono di libera circolazione e possono essere messo in commercio in Italia e in tutto il territorio dell'Unione Europea. Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione.

The above mentioned products, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union. This certificate is issued on the interested company's request according to the law and for exporting.



DIRETTORE DELL'UFFICIO
THE OFFICE DIRECTOR

Pietro Calamea

Pietro Calamea