

## DECLARATION OF CONFORMITY

Manufacturer (Name, department): Diagnostic Automation / Cortez Diagnostics, Inc.  
 Address: 21250 Califa St, Suite 102, Woodland Hills, CA 91367  
 and European authorized representative: CEpartner4U BV,  
 Address: Esdoornlaan 13, 3951DB Maarn, The Netherlands;  
 (on product labels printed as:  
 CEpartner4U , Esdoornlaan 13, 3951DB Maarn, The Netherlands. [www.cepartner4u.eu](http://www.cepartner4u.eu))

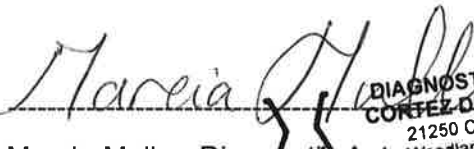

Product(s) (name, type or model/batch number, etc.):

Immunofluorescence Antibody Assay Kits, ELISA Kits, Rapid Test Products,  
 Chemiluminescence ImmunoAssays and Serology test. (See: appendix A)

The product(s) described above is in conformity with:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):  
 Conformity assessment procedure for CE marking:  
 Low risk devices: IVD Directive, Annex III (section 1 through 5)  
 Low risk devices for self-testing: IVD Directive, Annex III (section 1 through 6)  
 Notified Body: Lloyd's Register Quality Assurance, NB number # 0088

Woodland Hills, USA; 2015-09-28    
 Marcia Muller, Diagnostic Automation / Cortez Diagnostics, Inc  
 (Place & date of issue (yyyy-mm-dd)) (name; function and signature of manufacturer)

Declaration form: Standard ISO/IEC 17050-1:2010

vs. 2011-X

## Appendix A (Low Risk & Self Test Devices)

Date: 2013-12-19

### List of devices.

<b>Device group: Immunofluorescence Antibody Assay Kits (IFA-Kits)</b>					
Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
<b>Autoimmune Diseases and others:</b>	<b>Doc A_112002.pdf</b>				
ANA Rat Liver IFA Kit	210708	low risk	12 10 01 90 00		2003-11-12
ANA Rat Liver Slide Package	212506-SP 212508-SP	low risk	12 10 01 90 00		2003-11-12
ANA Mouse Kidney IFA Kit	22078D	low risk	12 10 01 90 00		2003-11-12
ANA Mouse Kidney Slide package	222508-SP	low risk	12 10 01 90 00		2003-11-12
ANA HEP-2 IFA Kit	230596, 231005D, 231005DE, 230512D,230512DE 231024	low risk	12 10 01 90 00		2003-11-12
ANA HEP-2 IFA Slide package	231096-SP,231024-SP 232505-SP, 232512-SP	low risk	12 10 01 90 00		2003-11-12
AMA IFA Kit	240806D	low risk	12 10 90 02 00		2003-11-12
AMA Slide package	242506-SP	low risk	12 10 90 02 00		2003-11-12
AAS IFA Kit	250608D	low risk	12 10 90 90 00		2003-11-12
AAS Rat Kidney Stomach Liver Tissue	250609D	low risk	12 10 90 90 00		2013-12-19
AAS Mouse Kidney Stomach Liver Tissue	250610D	low risk	12 10 90 90 00		2013-12-19
AAS Slide package	252508-SP	low risk	12 10 90 90 00		2003-11-12
ASMA IFA Kit	260806D	low risk	12 10 90 90 00		2003-11-12
ASMA IFA Slide package	262506-SP	low risk	12 10 90 90 00		2003-11-12

**Device group:**
**Immunofluorescence Antibody Assay Kits (IFA-Kits)**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
ATA IFA Kit	270806D	low risk	12 10 90 90 00		2003-11-12
ATA Slide package	272506-SP	low risk	12 10 90 90 00		2003-11-12
ASA IFA Kit	280806	low risk	12 10 90 90 00		2003-11-12
ASA Slide package	282506-SP	low risk	12 10 90 90 00		2003-11-12
ANCA – ethanol fixed	290060-entho	low risk	12 10 90 90 00		2003-11-12
ANCA – formalin fixed	290060-form	low risk	12 10 90 90 00		2003-11-12
Endomysial Antibody	300048 – 300096	low risk	12 10 90 16 00		2003-11-12
Reticulin IgA	310048-A – 310096-A	low risk	12 10 90 90 00		2003-11-12
Reticulin IgG	310048-G – 310096-G	low risk	12 10 90 90 00		2003-11-12
nDNA IFA Kit	320608 – 321204	low risk	12 10 90 90 00		2003-11-12
DNA Slide	322508-SP – 322504-SP	low risk	12 10 90 90 00		2003-11-12
<b>Bacterial Diseases:</b>	<b>Doc A_112002.pdf</b>				
Legionella Antibody IFA Kit (group 1-4)	331008-4	low risk	15 01 05 03 00		2003-11-12
Legionella Antibody IFA Kit (group 1)	331008-1	low risk	15 01 05 03 00		2003-11-12
Legionella Antibody IFA Kit (group 1-6)	331008-6D	low risk	15 01 05 03 00		2003-11-12
Legionella Antibody IFA Kit (group 1-4) slides	332508-4SP	low risk	15 01 05 03 00		2003-11-12
Legionella Antibody IFA Kit (group 1) slides	332508-1SP	low risk	15 01 05 03 00		2003-11-12
Legionella Antibody IFA Kit (group 1-6) slides	332508-6SP	low risk	15 01 05 03 00		2003-11-12
Mycoplasma Pneumonia IFA IgG Kit	341010-G	low risk	15 01 08 90 00		2003-11-12
Mycoplasma Pneumonia IFA Crown-Titre IgG Kit	341010-CTG	low risk	15 01 08 90 00		2003-11-12

**Device group:**
**Immunofluorescence Antibody Assay Kits (IFA-Kits)**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
Mycoplasma Pneumonia IFA IgM Kit	341010-M	low risk	15 01 08 90 00		2003-11-12
Mycoplasma Pneumonia IFA Crown-Titre IgM Kit	341010-CTM	low risk	15 01 08 90 00		2003-11-12
Mycoplasma Pneumonia IFA IgG Slides	342510-GSP	low risk	15 01 08 90 00		2003-11-12
Mycoplasma Pneumonia IFA Crown-Titre Slides	342510-CTGSP	low risk	15 01 08 90 00		2003-11-12
Mycoplasma Pneumonia IFA IgM Kit	341010-M	low risk	15 01 08 90 00		2003-11-12
Mycoplasma Pneumonia IFA crown-Titre IgM Slides	342510-CTMSP	low risk	15 01 03 90 00		2003-11-12
FTA-ABS Double Stain (Syphilis) IFA Kit	351010-DS	low risk	15 01 03 90 00		2003-11-12
FTA-ABS(Syphilis) IFA Kit	351010	low risk	15 01 03 90 00		2013-12-19
FTA-ABS (Syphilis) Titrable IFA Kit	351010-T	low risk	15 01 03 90 00		2003-11-12
FTA-ABS Slides	352510-SP	low risk	15 01 03 90 00		2003-11-12
FTA Slide mounting media	351003-MM	low risk	15 01 03 90 00		2003-11-12
B.Burdoferi (Lyme ) IgG/IgM IFA Kit	361010-G/M	low risk	15 01 06 03 00		2003-11-12
B.Burdoferi (Lyme ) IgG IFA Kit	361010-G	low risk	15 01 06 05 00		2003-11-12
B.Burdoferi (Lyme ) IgM IFA Kit	361010-M	low risk	15 01 06 06 00		2003-11-12
B.Burdoferi (Lyme ) IgG Slides	362510-GSP	low risk	15 01 06 05 00		2003-11-12
B.Burdoferi (Lyme ) IgM Slides	362510-MSP	low risk	15 01 06 06 00		2003-11-12
<b>Viral diseases:</b>					
HSV-1 IgG IFA Kit / Slides	382510-GSP	low risk	15 04 03 08 00		2003-11-12
HSV-1 IgM IFA Kit / Slides	382510-MSP	low risk	15 04 03 09 00		2003-11-12
HSV-2 IgG IFA Kit / Slides	392510-GSP	low risk	15 04 03 11 00		2003-11-12

**Device group:**
**Immunofluorescence Antibody Assay Kits (IFA-Kits)**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
HSV-2 IgM IFA Kit / Slides	392510-MSP	low risk	15 04 03 12 00		2003-11-12
EBV-VCA IgG Kit / slides	402510-GSP	low risk	15 04 04 90 00		2003-11-12
EBV-VCA IgM Kit / slides	402510-MSP	low risk	15 04 04 90 00		2003-11-12
EBV-EA IFA Kit/ Slides	402510-EASP	low risk	15 04 04 90 00		2003-11-12
EBV-NA IFA Kit / Slides	402510-NASP	low risk	15 04 04 90 00		2003-11-12
Measles IgG IFA Kit / Slides	412510-GSP	low risk	15 04 80 07 00		2003-11-12
Varicella-Zoster Virus IgG IFA Kit / Slides	422510-GSP	low risk	15 04 80 10 00		2005-06-21
HSV-1 IgG IFA Kit	381010-G	low risk	15 04 03 08 00		2008-06-01
HSV-1 IgM IFA Kit	381010-M	low risk	15 04 03 09 00		2008-06-01
HSV-2 IgG IFA Kit	391010-G	low risk	15 04 03 11 00		2008-06-01
HSV-2 IgM IFA Kit	391010-M	low risk	15 04 03 12 00		2008-06-01
EBV-VCA IgG IFA Kit	401010-G	low risk	15 04 04 90 00		2008-06-01
EBV-VCA IgM IFA Kit	401010-M,401005-MD	low risk	15 04 04 90 00		2008-06-01
EBV-EA IFA Kit	401010-EA	low risk	15 04 04 90 00		2008-06-01
EBV-NA IFA Kit	401010-NA	low risk	15 04 04 90 00		2008-06-01
Measles IgG IFA Kit	411010-G,250611D	low risk	15 04 80 07 00		2008-06-01
Varicella-Zoster Virus IgG IFA Kit	421010-G	low risk	15 04 80 10 00		2008-06-01
<b>Parasitic Diseases:</b>					
Chagas	431103-B60 , 341103- B40	low risk	15 05 10 02 00		2003-11-12
Echinococcosis	431203-B60 , 431203- B40	low risk	15 05 10 04 00		2003-11-12



Device group:

**Immunofluorescence Antibody Assay Kits (IFA-Kits)**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
Trichinosis	431303-B60	low risk	15 05 10 90 00		2003-11-12

**Device group:  
 ELISA KITS**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
<b>Autoimmune Disease and others</b>	<b>Doc B_052003.pdf</b>				
Anti CCP	3175-17	low risk	12 10 01 03 00		2012-05-23
Transglutaminase IgG	3174-17	low risk	12 10 90 21 00		2012-05-23
Transglutaminase IgA	3173-17	low risk	12 10 90 21 00		2012-05-23
ANA Screen	5102-2	low risk	12 10 01 01 00		2003-11-12
ENA Profile (12 test kits) Sm/RNP, Sm, Jo-1, Scl-70, SS-A, SS-B	2506-2	low risk	12 10 01 90 00		2003-11-12
ENA Combined Screen (6 antigens) Sm/RNP, Sm, Jo-1, Scl-70, SS-A, SS-B	2552-2	low risk	12 10 01 02 00		2003-11-12
Sm/RNP	2558-2	low risk	12 10 01 11 00		2003-11-12
Sm	2570-2	low risk	12 10 01 11 00		2003-11-12
Jo-1	2557-2	low risk	12 10 01 08 00		2003-11-12
Scl-70	2559-2	low risk	12 10 01 10 00		2003-11-12
SS-A (Ro)	2555-2	low risk	12 10 01 12 00		2003-11-12
SS-B (La)	2556-2	low risk	12 10 01 13 00		2003-11-12
dsDNA	2553-1, 2553-4	low risk	12 10 01 05 00		2003-11-12
Cardiolipin IgG	1491-2, 1491-11	low risk	12 10 01 90 00		2003-11-12
Cardiolipin IgM	1492-2, 1492-11	low risk	12 10 01 90 00		2003-11-12
Cardiolipin IgA	1493-2, 1493-11	low risk	12 10 01 90 00		2003-11-12
Cardiolipin IgG, A, M	1490-1	low risk	12 10 01 90 00		2003-11-12
Histone	2571-1	low risk	12 10 01 07 00		2003-11-12
Rheumatoid Factor (RF)	2550-1	low risk	12 11 01 10 00		2003-11-12
Mitochondria	1420-1	low risk	12 10 90 02 00		2003-11-12

**Device group:  
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Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
Thyroglobulin	1421-1	low risk	12 04 01 08 00		2003-11-12
Thyroid Microsomal	1422-1	low risk	12 10 03 01 00		2003-11-12
Ribosomal P	1431-1	low risk	12 10 90 20 00		2003-11-12
PR3 (c-ANCA)	1445-1	low risk	12 10 90 10 00		2003-11-12
ANCA screen IgG	1681-2	low risk	12 10 01 90 00		2003-11-12
MPO ,Myeloperoxidase (p-ANCA)	1441-2	low risk	12 10 90 09 00		2003-11-12
Gliadin IgG	1021-2	low risk	12 10 90 06 00		2003-11-12
Gliadin IgA	1022-2	low risk	12 10 90 06 00		2003-11-12
TPO - 2008-06-01	1446-2	low risk	12 10 03 01 00		2008-06-01
<b>Cancer (tumor markers)</b>	Doc B_052003.pdf				
Prostatic Acid Phosphatase (PAP)	4227-11	low risk	12 03 01 37 00		2003-11-12
<b>b2-Microglobulin</b>	4200-18, 4200-16	low risk	12 03 90 02 00		2003-11-12
AFP (Alpha Fetoprotein)	5101-16	low risk	12 03 90 01 00		2003-11-12
CEA	5201-16	low risk	12 03 01 31 00		2003-11-12
CA-15-3	6333-16	low risk	12 03 01 02 00		2003-11-12
CA-12-5	6502-16	low risk	12 03 01 06 00		2003-11-12
CA-19-9	6909-16	low risk	12 03 01 03 00		2003-11-12
CA-242	6335Z	low risk	12 03 01 08 00		2003-11-12
<b>NSE</b>	6334-16	low risk	12 03 90 08 00		2003-11-12
Ferritin	1606-18, 1601-16	low risk	12 07 01 02 00		2003-11-12
Free Beta HCG	4221-16	low risk	12 03 01 90 00		2003-11-12



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Device types	Document / page Catalog	Risk classification	EDMS code	CE-certificate	First CE-marking
<b>Cardiac</b>	Doc B_052003.pdf				
Digoxin	1669-15	low risk	12 08 01 01 00		2005-11-11
CK-MB	1005-15	low risk	11 01 01 14 00		2003-11-12
Troponin I	1105-18	low risk	12 70 13 03 00		2003-11-12
Myoglobin	1667-18	low risk	12 13 01 05 00		2003-11-12
C-Reactive Protein (CRP)	1668-18	low risk	12 11 01 09 00		2003-11-12
OLAB	2032	low risk	12 13 01 90 00		2003-11-12
Endothelin	2052	low risk	12 13 01 90 00		2003-11-12
MGP	2062	low risk	12 13 01 90 00		2003-11-12
Big ET	2072	low risk	12 13 01 90 00		2003-11-12
Pro-ANP(1098)	2892	low risk	12 13 01 01 00		2003-11-12
Nt-proBNP	2852	low risk	12 13 01 90 00		2003-11-12
OxyStat	5007	low risk	12 13 01 90 00		2003-11-12
<b>Allergy</b>	Doc B_052003.pdf				
<b>Total Human IgE</b>	1801-18, 1801-16	low risk	12 02 01 02 00		2003-11-12
Total Human IgA	1802-9	low risk	12 02 01 08 00		2003-11-12
Total Human IgG	1803-9	low risk	12 02 01 09 00		2003-11-12
Total Human IgM	1804-9	low risk	12 02 01 90 00		2003-11-12
<b>Human Allergen Specific IgE</b>	1805-9	low risk	12 02 01 03 00		2003-11-12
Human Allergy Panel	1806-9	low risk	12 02 01 02 00		2003-11-12
<b>Bone Metabolism</b>	Doc B_052003.pdf				

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Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
Intact PTH	1735-6	low risk	12 06 03 13 00		2003-11-12
125 Dihydroxyvitamin D	1737Z	low risk	12 06 03 90 00		2003-11-12
25- Hydroxyvitamin D	1738-7	low risk	12 06 03 10 00		2003-11-12
Osteoprotegerin (OPG)	2402-7	low risk	12 06 03 90 00		2003-11-12
sRANKL	2422-7	low risk	12 06 03 90 00		2003-11-12
<b>Fertility (Reproduction Function)</b>	Doc B_052003.pdf				
Human Growth Hormone (HGH)	1901-16, 1901-18	low risk	12 06 04 02 00		2003-11-12
HCG Visual	4102-16	low risk	12 05 02 05 00		2003-11-12
Beta hCG	4201-16, 4201-18	low risk	12 05 02 06 00		2003-11-12
FSH	4224-16, 4224-18	low risk	12 05 01 04 00		2003-11-12
LH	4225-16, 4225-18	low risk	12 05 01 05 00		2003-11-12
Prolactin (PRL)	4226-16, 4226-18	low risk	12 05 01 08 00		2005-06-21
PAPP-A	4229-6	low risk	12 05 02 10 00		2008-06-01
<b>Steroid</b>	Doc B_052003.pdf				
Cortisol	6101-15	low risk	12 06 02 04 00		2003-11-12
Estradiol	2046-18	low risk	12 05 01 03 00		2003-11-12
DHEA-S	2055-17	low risk	12 05 01 02 00		2003-11-12
DHEA	2056-6	low risk	12 05 01 02 00		2003-11-12
Progesterone	2077-18	low risk	12 05 01 06 00		2003-11-12
Testosterone	2095-18	low risk	12 05 01 10 00		2003-11-12
Free Testosterone	2924-17	low risk	12 05 01 10 00		2003-11-12

**Device group:  
ELISA KITS**

Device types	Document / page Catalog	Risk classification	EDMS code	CE-certificate	First CE-marking
Free Testosterone 2G	3178-17	low risk	12 05 01 10 00		2003-11-12
Androstenedione (ASD)	1038-17	low risk	12 05 01 01 00		2003-11-12
Free Estriol	3171-17	low risk	12 05 02 03 00		2012-05-23
Total Estriol	3172-17	low risk	12 05 02 02 00		2003-11-12
17-alpha hydroxy Progesterone	1292-17	low risk	12 06 05 04 00		2005-06-21
<b>Thyroid</b>	Doc B_052003.pdf				
T3	3144-16, 3144-18	low risk	12 04 01 05 00		2003-11-12
T4	3149-16, 3149-18	low risk	12 04 01 07 00		2003-11-12
TSH	3122-16, 3122-18	low risk	12 04 01 11 00		2003-11-12
U-TSH	3123-16, 3123-18	low risk	30 31 800 00		2003-11-12
Free T4	3146-15	low risk	12 04 01 02 00		2003-11-12
Free T3	3148-15	low risk	12 04 01 01 00		2003-11-12
T Uptake	3176-15	low risk	12 04 01 06 00		2003-11-12
NNT4 (NeoNatal T4)	3150-15	low risk	12 04 01 12 00		2003-11-12
NTSH ( NeoNatal TSH)	3124-15	low risk	12 04 01 90 00		2005-11-11
<b>Infectious Diseases</b>	Doc B_052003.pdf				
Adenovirus IgA	6103-8	low risk	15 04 80 01 00		2003-11-12
Adenovirus IgG	6101-8	low risk	15 04 80 01 00		2003-11-12
Adenovirus IgM	6102-8	low risk	15 04 80 01 00		2003-11-12
Influenza A IgA	5104-8	low risk	15 01 90 10 00		2003-11-12
Influenza A IgG	5105-8	low risk	15 01 90 10 00		2003-11-12

**Device group:  
ELISA KITS**

Device types	Document / page Catalog	Risk classification	EDMS code	CE-certificate	First CE-marking
Influenza A IgM	5106-8	low risk	15 01 90 10 00		2003-11-12
Influenza B IgA	5107-8	low risk	15 01 90 10 00		2003-11-12
Influenza B IgG	5108-8	low risk	15 01 90 10 00		2003-11-12
Influenza B IgM	5109-8	low risk	15 01 90 10 00		2003-11-12
TB IgA	5110-8	low risk	15 90 90 90 00		2003-11-12
TB IgG	5111-8	low risk	15 90 90 90 00		2003-11-12
TB IgM	5112-8	low risk	15 90 90 90 00		2003-11-12
Herpes Simplex 1 IgG (HSV1 IgG)	1401-11, 1401-2	low risk	15 04 03 08 00		2003-11-12
Herpes Simplex 1 IgM (HSV1 IgM)	1402-11	low risk	15 04 03 09 00		2003-11-12
Herpes Simplex 2 IgG (HSV2 IgG)	1403-2, 1403-11	low risk	15 04 03 11 00		2003-11-12
Herpes Simplex 2 IgM (HSV2 IgM)	1404-11, 1404-2	low risk	15 04 03 12 00		2003-11-12
Herpes Simplex 1,2 IgG (HSV1,2 IgG)	1443-11	low risk	15 04 03 90 00		2003-11-12
Herpes Simplex 1,2 IgM (HSV1,2 IgM)	1444-2, 1444-11	low risk	15 04 03 90 00		2003-11-12
Epstein Barr Virus VCA IgG (EBV, VCA IgG)	1405-2	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus VCA IgM (EBV, VCA IgM)	1406-2	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus Early Antigen (EA) IgG	1415-11, 1415-2	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus Nuclear Antigen (EBNA) IgG	1425-1	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus Nuclear Antigen (EBNA) IgM	1426-1	low risk	15 04 04 90 00		2003-11-12
Measles IgG	1408-1, 1408-11	low risk	15 04 80 07 00		2003-11-12
Measles IgM	1409-1, 1409-11	low risk	15 04 80 07 00		2003-11-12
Mumps IgG	1410-1, 1410-11	low risk	15 04 80 08 00		2003-11-12

**Device group:  
ELISA KITS**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
Mumps IgM	1411-11, 1411-1	low risk	15 04 80 08 00		2003-11-12
Mycoplasma pneumonia IgG	8042-2	low risk	15 01 08 90 00		2003-11-12
Mycoplasma pneumonia IgM	8043-2	low risk	15 01 08 90 00		2003-11-12
Syphilis (TPA) IgG	1463-1	low risk	15 01 03 05 00		2003-11-12
Syphilis (TPA) IgM	1464-6	low risk	15 01 03 06 00		2003-11-12
Legionella G/M/A	1651-2	low risk	15 01 05 01 00		2003-11-12
H.pylori IgG	1503-2, 1503-11	low risk	15 01 04 01 00		2003-11-12
H.pylori IgA	1505-11	low risk	15 01 04 01 00		2003-11-12
H-Pylori IgM	1504-11	low risk	15 01 04 01 00		2003-11-12
Varicella-Zoster IgG	1412-1	low risk	15 04 80 10 00		2003-11-12
Varicella-Zoster IgM	1413-1	low risk	15 04 80 10 00		2003-11-12
Brucella IgG	1501-8	low risk	15 01 90 01 00		2003-11-12
Brucella IgM	1502-8	low risk	15 01 90 01 00		2003-11-12
Brucella IgA	1507-8	low risk	15 01 90 01 00		2003-09-08
HEV IgM	1876-12	low risk	15 02 05 06 00		2003-11-12
HEV Ab	1877-12	low risk	15 02 05 04 00		2003-11-12
HGV Ab	1887-12	low risk	15 02 07 04 00		2003-11-12
HAV IgM	1718-12	low risk	15 02 01 06 00		2003-11-12
Lyme Disease IgG	1428-2	low risk	15 01 06 05 00		2008-06-01
Lyme Disease IgM	1424-2	low risk	15 01 06 05 00		2008-06-01
Lyme Disease IgG, M	1423-2	low risk	15 01 06 05 00		2008-06-01



**Device group:  
ELISA KITS**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE- marking
Bordetella Pertussis IgA	5117-8	low risk	15 01 90 07 00		2008-06-01
Bordetella Pertussis IgG	5118-8	low risk	15 01 90 07 00		2008-06-01
Bordetella Pertussis IgM	5119-8	low risk	15 01 90 07 00		2008-06-01
RSV IgA	5113-8	low risk	15 04 80 04 00		2008-06-01
RSV IgG	5114-8	low risk	15 04 80 04 00		2008-06-01
RSV IgM	5115-8	low risk	15 04 80 04 00		2008-06-01

## Device group: ELISA KITS

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
<b>Parasitology Antibody Detection</b>	Doc B_052003.pdf				
Schistosoma IgG	8209-35	low risk	15 05 10 06 00		2003-11-12
Chagas	8100-35	low risk	15 05 10 02 00		2003-11-12
Cysticercosis IgG (T.Solium)	8105-35	low risk	15 05 10 90 00		2003-11-12
Dengue IgG/IgM	8115-35	low risk	15 04 80 11 00		2003-11-12
Dengue IgG	8116-35	low risk	15 04 80 11 00		2003-11-12
Dengue IgM	8117-35	low risk	15 04 80 11 00		2003-11-12
Diphtheria IgG	8118-35	low risk	15 05 10 90 00		2003-11-12
E. histolytica IgG (Amebiasis)	8201-35	low risk	15 05 10 90 00		2003-11-12
Echinococcus IgG	8202-35	low risk	15 05 10 04 00		2003-11-12
Leishmania	8203-35	low risk	15 05 10 05 00		2003-11-12
Leptospira IgG	8204-35	low risk	15 01 90 04 00		2003-11-12
Leptospira IgM	8208-35	low risk	15 01 90 04 00		2003-11-12
Tetanus IgG	8205-35	low risk	15 01 90 09 00		2003-11-12
Toxocara IgG	8206-35	low risk	15 05 10 90 00		2003-11-12
Trichinella IgG	8207-35	low risk	15 05 10 90 00		2003-11-12
Japanese Encephalitis IgG	8402-25	low risk	15 04 80 90 00		2005-11-09
Japanese Encephalitis IgM	8403-25	low risk	15 04 80 90 00		2005-11-09
West Nile IgG	8400-25	low risk	15 04 80 90 00		2005-11-09
West Nile IgM	8401-25	low risk	15 04 80 90 00		2005-11-09
S. typhus IgG	8406-25	low risk	15 01 40 90 00		2007-01-05

## Device group: ELISA KITS

Device types	Document / page Catalog	Risk classification	EDMS code	CE-certificate	First CE-marking
S. typhus IgM	8405-25	low risk	15 01 40 90 00		2007-01-05
Ascaris IgG	8212-35	low risk	15 05 10 90 00		2011-25-07
<b>Parasitology Antigen detection</b>	Doc B_052003.pdf				
C.difficile	8308-3	low risk	15 05 10 90 00		2003-11-12
Adenovirus (Fecal)	8300-3	low risk	15 04 80 01 00		2003-11-12
<b>Strongyloides IgG</b>	8319-35	low risk	15 05 10 90 00		2008-06-01
Cryptosporidium (Fecal)	8301-3	low risk	14 05 02 03 00		2003-11-12
E. Coli 0157 (Fecal)	8302-3	low risk	15 01 15 90 00		2003-11-12
E. histolytica/dispar	8307-3	low risk	14 05 02 90 00		2003-11-12
E. Coli Verotoxin (Fecal)	8303-3	low risk	15 01 15 90 00		2003-11-12
Giardia	8304-3	low risk	15 05 10 08 00		2003-11-12
Legionella Urinary Antigen (Urine)	8305-3	low risk	15 01 05 01 00		2003-11-12
Rotavirus (Fecal)	8306-3	low risk	15 04 80 06 00		2003-11-12
<b>Diabetes</b>	Doc B_052003.pdf				
Insulin	1606-15	low risk	12 06 01 03 00		2003-11-12
C-peptide	1293-15	low risk	12 06 01 01 00		2003-11-12
<b>Food</b>					
Vitamin H (Biotin)	1741-8	low risk	12 07 02 90 00		2003-11-12
Vitamin B12	1739-8	low risk	12 07 02 04 00		2003-11-12
Histamine	1738-8	low risk	12 02 01 01 00		2003-11-12
Folate (Folic Acid)	1736-8	low risk	12 07 01 03 00		2003-11-12



**Device group:  
ELISA KITS**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
Others	Doc B_052003.pdf				
(a)	1740-9	low risk	12 01 04 21 00		2003-11-12
anti-Tetanus Toxoid	8900-28	low risk	15 01 90 09 00		2005-06-21
Cholera Toxoid IgG	1760-28	low risk	15 04 80 90 00		2003-11-12
Dengue NS1 Antigen Elisa	8404-25	low risk	15 04 80 11 00		2012-06-26
Diabetes					
Anti-HB12	3125-15	low risk	12 07 02 04 00		2011-09-26
Anti-HB late	3127-15	low risk	12 07 01 03 00		2010-06-29
Anti-Transferrin Soluble Receptor	3126-15	low risk	12 07 01 06 00		2010-06-29

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
<b>Allergy</b>	Doc C_052003.pdf				
OneStep IgE Serum RapiCard™ InstaTest	15150-1	low risk	12 02 01 02 00		2003-11-12
<b>Cancer</b>	Doc C_052003.pdf				
Hemo Fecal Occult Blood RapiCard™ InstaTest	13010-1	low risk	12 03 90 04 00		2003-11-12
Hemo Fecal Occult Blood RapiDip™ InstaTest (5mm Strip)	13020-1	low risk	12 03 90 04 00		2003-11-12
Fecal Occult Blood Test (Uncut Sheet)	13010-SHU	low risk	12 03 90 04 00		2003-11-12
FOB 10X Stock Solution(1 ltr for 5000 tests)	13010-BUFA	low risk	12 03 90 04 00		2003-11-12
<b>CEA</b>	Doc C_052003.pdf				
One Step CEA Serum/Whole Blood RapiCard™ InstaTest	13059-1	low risk	12 03 01 31 00		2003-11-12
OneStep CEA Serum RapiCard™ InstaTest	13060-1	low risk	12 03 01 31 00		2003-11-12
OneStep CEA Serum RapiDip™ InstaTest (5mmStrip)	13061-1	low risk	12 03 01 31 00		2003-11-12
CEA Serum (Uncut Sheet, Cassette)	13060-SHU	low risk	12 03 01 31 00		2003-11-12
CEA Serum (Uncut Sheet, Strip)	13061-SHU	low risk	12 03 01 31 00		2003-11-12
<b>AFP</b>	Doc C_052003.pdf				
One Step AFP Serum/Whole Blood RapiCard™ InstaTest	13039-1	low risk	12 03 90 01 00		2003-11-12
OneStep AFP Serum RapiCard™ InstaTest	13040-1	low risk	12 03 90 01 00		2003-11-12
OneStep AFP Serum RapiDip™ InstaTest (5mm Strip)	13041-1	low risk	12 03 90 01 00		2003-11-12
AFP Serum (Uncut Sheet, Cassette)	13040-SHU	low risk	12 03 90 01 00		2003-11-12
<b>Cardiac markers</b>	Doc C_052003.pdf				
C-Reactive Protein (CRP) Serum RapiCard™ InstaTest	166770-1	low risk	12 70 11 01 00		2003-11-12

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep Troponin I Serum RapiCard™ InstaTest	166771-1	low risk	12 70 01 53 00		2003-11-12
One Step Myoglobin Serum RapiCard™ InstaTest	166773-1	low risk	12 70 13 02 00		2003-11-12
One Step CK-MB Serum RapiCard InstaTest	166776-1	low risk	12 13 01 02 00		2003-11-12
One Step 3 in 1 Troponin I/Myoglobin/CK-MB Serum RapiCard InstaTest	166778-1	low risk	12 70 13 90 00		2003-11-12
C-Reactive Protein (CRP) RapiCard™ InstaTest (Serum/Whole Blood)	166800-1	low risk	12 70 11 01 00		2003-11-12
OneStep Troponin I Serum/Whole Blood RapiCard™ InstaTest	166772-1	low risk	12 70 01 53 00		2003-11-12
OneStep Myoglobin Serum/Whole Blood RapiCard™ InstaTest	166774-1	low risk	12 70 13 02 00		2003-11-12
One Step CK-MB Serum/Whole Blood RapiCard InstaTest	166777-1	low risk	12 13 01 02 00		2003-11-12
One Step 3 in 1 Troponin I/Myoglobin/CK-MB ( Serum/Whole Blood RapiCard InstaTest)	166779-1	low risk	12 70 13 90 00		2003-11-12
Troponin I Serum (Uncut Sheet)	176771-SHU	low risk	12 70 01 53 00		2003-11-12
CK-MB serum (Uncut Sheet)	166776-SHU	low risk	12 13 01 02 00		2003-11-12
Myoglobin Serum (Uncut Sheet)	166773-SHU	low risk	12 70 13 02 00		2003-11-12
Troponin I Serum/Whole Blood (Uncut Sheet)	176772-SHU	low risk	12 70 01 53 00		2003-11-12
Myoglobin Serum/Whole Blood (Uncut Sheet)	166774-SHU	low risk	12 70 13 02 00		2003-11-12
CK-MB Whole Blood/Serum ( Uncut Sheet)	166777-SHU	low risk	12 13 01 02 00		2003-11-12
<b>Drug Test</b>	<b>Doc C_052003.pdf</b>				
OneStep Oxycodone Urine RapiCard™ InstaTest	121002-1	low risk	12 70 09 90 00		2008-06-01
OneStep Oxycodone Urine RapiDip™ InstaTest	121001-1	low risk	12 70 09 90 00		2008-06-01
OneStep MultiDrug Urine RapiDip™ InstaTest	120958-1	low risk	12 70 09 90 00		2008-06-01
OneStep MultiDrug Urine RapiCard™ InstaTest	120959-1	low risk	12 70 09 90 00		2008-06-01

### Device group: RAPIDTEST

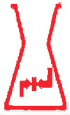
Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep Buprenorphine Urine RapiDip™ InstaTest	121003-1	low risk	12 70 09 90 00		2003-11-12
OneStep Buprenorphine Urine RapiCard™ InstaTest	121004-1	low risk	12 70 09 90 00		2003-11-12
OneStep Alcohol Urine RapiDip InstaTest	121012-1	low risk	12 09 02 07 00		2013-12-19
OneStep Alcohol Saliva InstaTest	121000-1	low risk	12 09 02 07 00		2003-11-12
OneStep Amphetamine Urine RapiCard™ InstaTest	121020-1	low risk	12 70 09 01 00		2003-11-12
OneStep Barbiturates Urine RapiCardstaTest	121060-1	low risk	12 70 09 03 00		2003-11-12
OneStep Benzodiazepine Urine RapiCard™ InstaTest	121061-1	low risk	12 70 09 04 00		2003-11-12
OneStep Cocaine Urine RapiCard™ InstaTest	121040-1	low risk	12 70 09 06 00		2003-11-12
OneStep MDMA(Ecstasy) RapiCard InstaTest	121030-1	low risk	12 09 01 02 00		2003-11-12
OneStep Methamphetamine Urine RapiCard™ InstaTest	121035-1	low risk	12 09 01 02 00		2003-11-12
OneStep Methadone Urine RapiCard™ InstaTest	121005-1	low risk	12 70 09 07 00		2003-11-12
OneStep Marijuana Urine RapiCard™ InstaTest	121027-1	low risk	12 70 09 05 00		2003-11-12
OneStep Opiates/Heroin/Morphine Urine RapiCard™ InstaTest	121058-1	low risk	12 70 09 08 00		2003-11-12
OneStep Phencyclidine Urine RapiCard™ InstaTest	121065-1	low risk	12 70 09 09 00		2003-11-12
OneStep Tricyclic Antidepressants( TCA ) RapiCard™ InstaTest	121025-1	low risk	12 70 09 10 00		2003-11-12
OneStep 6-Drug RapiCard™ InstaTest, (MET,MOR,THC,AMP,COC,BZD)	121050-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiCard™ InstaTest ,(MAD, MOR,THC,AMP,COC,BZD)	121039-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiCard™ InstaTest, ,(Any Drug Combination)	121067-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiCard™ InstaTest, (MET, MOR,THC,COC)	121038-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiCard InstaTest,(AMP,COC,MOR,THC)	121072-1	low risk	12 70 09 90 00		2003-11-12

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep 2-Drug RapiCard™ InstaTest (MOR/MET)	121037-1	low risk	12 70 09 90 00		2003-11-12
OneStep Amphetamine Urine RapiDip™ InstaTest	121021-1	low risk	12 70 09 01 00		2003-11-12
OneStep Barbiturates Urine RapiDip™ InstaTest	121062-1	low risk	12 70 09 03 00		2003-11-12
OneStep Benzodiazepine Urine RapiDip™ InstaTest	121063-1	low risk	12 70 09 04 00		2003-11-12
OneStep Cocaine Urine RapiDip™ InstaTest	121041-1	low risk	12 70 09 06 00		2003-11-12
OneStep MDMA(Ecstasy) RapiDip InstaTest	121033-1	low risk	12 09 01 02 00		2003-11-12
OneStep Methamphetamine Urine RapiDip™ InstaTest	121036-1	low risk	12 09 01 02 00		2003-11-12
OneStep Marijuana Urine RapiDip™ InstaTest	121028-1	low risk	12 70 09 05 00		2003-11-12
OneStep Methadone Urine RapiDip™ InstaTest	121091-1	low risk	12 70 09 07 00		2003-11-12
OneStep Opiates/Heroin/Morphine Urine RapiDip™ InstaTest	121059-1	low risk	12 70 09 08 00		2003-11-12
OneStep Phencyclidine Urine RapiDip™ InstaTest	121080-1	low risk	12 70 09 09 00		2003-11-12
OneStep Tricyclic Antidepressants( TCA ) RapiDip™ InstaTest	121031-1	low risk	12 70 09 10 00		2003-11-12
OneStep 12-Drug RapiDip™ InstaTest,(Any Drug Combination)	150203-1	low risk	12 70 09 90 00		2003-11-12
OneStep 11-Drug RapiDip™ InstaTest,(Any Drug Combination)	150202-1	low risk	12 70 09 90 00		2003-11-12
OneStep 10-Drug RapiDip™ InstaTest,(Any Drug Combination)	121097-1	low risk	12 70 09 90 00		2003-11-12
OneStep 10-Drug RapiDip™ InstaTest, (AMP,BAR,BZD,COC,MDMA,THC,MET HADONE,METH,OPI,PCP)	120313-1	Low risk	12 70 09 90 00		2010-7-16
OneStep 9-Drug RapiDip™ InstaTest,(Any Drug Combination)	121068-1	low risk	12 70 09 90 00		2003-11-12
OneStep 8-Drug RapiDip™ InstaTest,(Any Drug Combination)	121069-1	low risk	12 70 09 90 00		2003-11-12
OneStep 7-Drug RapiDip™ InstaTest,(Any Drug Combination)	121103-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest, (AMP,BAR,BZD,COC,MOR,THC)	121081-1	low risk	12 70 09 90 00		2003-11-12

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep 6-Drug RapiDip™ InstaTest, (MET, MOR, THC, AMP, COC, BZD)	121048-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest,(MAD, MOR, THC, AMP, COC, BZD)	121026-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest, (AMP,COC,MET,MOR,PCP,THC)	120610-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest,(AMP,BAR,COC,MET,MOR,T HC)	120620-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest,(BAR,BZD,COC,MAD,MOR,T HC)	120625-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest,(AMP,BZD,COC,MET,MAD,M OR)	120461-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest, (AMP,BAR,BZD,COC,MET,MOR)	120365-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest, (BZD,COC,MAD,MET,MOR,THC)	120460-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest, (AMP,BAR,BZD,COC,MET,THC)	120645-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest,(THC, PCP, MOR, COC, AMP)	121045-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (AMP,BZD,COC,MAD,MOR)	121046-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (COC,MET,MOR,PCP,THC)	121051-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (BAR,COC,MET,MOR,THC)	121052-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (AMP, BAR, BZD, MOR, THC)	121053-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (AMP,COC,MET,MOR,THC)	120500-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (BZD,MAD,MET,MOR,THC)	120515-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (BZD,MET,MOR,PCP,THC)	120520-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiDip™ InstaTest, (AMP,BZD,COC,MOR,THC)	120535-1	low risk	12 70 09 90 00		2003-11-12



**Device group:  
 RAPIDTEST**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep 5-Drug RapiDip™ InstaTest, (AMP,BZD,COC,MOR,MET)	120537-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (AMP, COC, MOR, THC)	121044-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (COC, MOR, PCP, THC)	121034-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (COC,MET,MOR,THC)	121082-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (AMP,BZD,MET,THC)	120410-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (AMP,BAR,COC,THC)	120415-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (AMP,BZD,COC,THC)	120420-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (AMP,COC,MET,THC)	120425-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (BAR,BZD,MOR,PCP)	120430-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiDip™ InstaTest, (BZD,COC,MOR,THC)	120435-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug RapiDip™ InstaTest, (AMP, MOR, THC)	121054-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug RapiDip™ InstaTest, (COC, MOR, THC)	121055-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug RapiDip™ InstaTest, (BAR, BZD, PCP)	121095-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug RapiDip™ InstaTest, (AMP,COC,THC)	120305-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug RapiDip™ InstaTest, (MET,MOR,THC)	120056-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug RapiDip™ InstaTest, (BAR,MAD,PCP)	120315-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug RapiDip™ InstaTest, (BZD,MAD,MOR)	120320-1	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug RapiDip™ InstaTest (THC, COC)	121043-1	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug RapiDip™ InstaTest (MOR, MET)	121042-1	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug RapiDip™ InstaTest (COC,MOR)	121032-1	low risk	12 70 09 90 00		2003-11-12

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep 2-Drug RapiDip™ InstaTest (MET,THC)	121049-1	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug RapiDip™ InstaTest (BAR,BZD)	121057-1	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug RapiDip™ InstaTest (MOR,THC)	121111-1	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug RapiDip™ InstaTest (MAD,MOR)	120215-1	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug RapiDip™ InstaTest (BZD,MOR)	120225-1	low risk	12 70 09 90 00		2003-11-12
Drug check NoStep RapiCup	Doc C_052003.pdf				
OneStep 10-Drug RapiCup InstaTest (Any Combination)	121112-1	low risk	12 70 09 90 00		2003-11-12
OneStep 9-Drug RapiCup InstaTest (Any Combination)	121109-1	low risk	12 70 09 90 00		2003-11-12
OneStep 8-Drug RapiCup InstaTest (Any Combination)	121122-1	low risk	12 70 09 90 00		2003-11-12
OneStep 7-Drug RapiCup InstaTest (Any Combination)	121121-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiCup InstaTest (Any Combination)	121108-1	low risk	12 70 09 90 00		2003-11-12
OneStep 5-Drug RapiCup InstaTest (Any Combination)	121107-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug RapiCup InstaTest (Any Combination)	121087-1	low risk	12 70 09 90 00		2003-11-12
RapiCup 6Test InstaCup, ( Any Combination )	120600	low risk	12 70 09 90 00		2003-11-12
RapiCup 5Test InstaCup, ( Any Combination )	120500	low risk	12 70 09 90 00		2003-11-12
RapiCup 4Test InstaCup, ( Any Combination )	120400	low risk	12 70 09 90 00		2003-11-12
OneStep 2-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123000-1	low risk	12 70 09 90 00		2003-11-12
OneStep 3-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123001-1	low risk	12 70 09 90 00		2003-11-12
OneStep 4-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123002-1	low risk	12 70 09 90 00		2003-11-12



### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep 5-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123003-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123004-1	low risk	12 70 09 90 00		2003-11-12
OneStep 7-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123005-1	low risk	12 70 09 90 00		2003-11-12
OneStep 8-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123006-1	low risk	12 70 09 90 00		2003-11-12
OneStep 9-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123007-1	low risk	12 70 09 90 00		2003-11-12
OneStep 10-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123008-1	low risk	12 70 09 90 00		2003-11-12
OneStep 11-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	123009-1	low risk	12 70 09 90 00		2003-11-12
<b>Infectious Diseases and others</b>	Doc C_052003.pdf				
<b>Legionella Antigen</b>					
Legionella Urinary Antigen Test (Urine)	176075-1	low risk	15 01 05 01 00		2008-06-01
<b>Adeno/Rotavirus</b>					
OneStep Adeno/Rotavirus Antigen RapiCard™ InstaTest ( Cassette)	176067-1	low risk	15 04 80 00		2009-02-21
<b>Adeno</b>					
OneStep Adeno Antigen RapiCard™ InstaTest ( Cassette)	176068-1	low risk	15 04 80 00		2009-02-21
<b>Adeno/Rotavirus</b>					
OneStep Rotavirus Antigen RapiCard™ InstaTest ( Cassette)	176066-1	low risk	15 04 80 00		2009-02-21
<b>Chagas</b>					

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
Chagas Two Spot RapiDip™ InstaTest (Serum/Plasma Test)	174105-1	low risk	15 05 10 02 00		2003-11-12
OneStep Chagas RapiDip™ Instatest	146119-25	low risk	14 70 01 90 00		2005-11-09
<b>Gonorrhea</b>	Doc C_052003.pdf				
OneStep Gonorrhea RapiCard™ InstaTest (Cassette Swab Test)	176510-1	low risk	15 05 10 90 00		2003-11-12
OneStep Gonorrhea RapiDip™ InstaTest (5mm Strip Swab Test)	176512-1	low risk	15 05 10 90 00		2003-11-12
<b>Leishmania</b>					
Onestep Leishmania RapiDip™ InstaTest (Serum Test)	176070-1	low risk	15 05 10 05 00		2003-11-12
Leishmania Two spot Rapid Test (Serum/Plasma Test)	176071-1	low risk	15 05 10 05 00		2003-11-12
<b>Syphilis</b>	Doc C_052003.pdf				
OneStep Syphilis RapiCard™ InstaTest (Cassette Serum Test)	176500-1	low risk	15 70 01 05 00		2003-11-12
OneStep Syphilis RapiDip™ InstaTest (5mm Strip Serum Test)	176502-1	low risk	15 70 01 05 00		2003-11-12
OneStep Syphilis RapiCard™ InstaTest (Cassette WB, Serum, Plasma)	176501-1	low risk	15 70 01 05 00		2003-11-12
<b>Mono</b>	Doc C_052003.pdf				
OneStep Mononucleosis RapiCard™ InstaTest (Cassette Serum Test)	176522-1	low risk	15 70 90 03 00		2003-11-12
<b>Strep A</b>					
OneStep Strep A RapiCard™ InstaTest (Cassette Swab Test)	176550-1	low risk	15 70 01 03 00		2003-11-12
Strep A (Uncut Sheet)	176550-SHU	low risk	15 70 01 03 00		2003-11-12
<b>H. Pylori</b>					
OneStep H. Pylori RapiCard™ InstaTest, (Cassette Serum/Whole Blood Test)	118562-1	low risk	15 70 01 02 00		2003-11-12
OneStep H. Pylori RapiCard™ InstaTest (Cassette Serum Test)	118561-1	low risk	15 70 01 02 00		2003-11-12

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep H. Pylori Antigen RapiCard™ InstaTest Cassette	118564-1-23	low risk	15 01 04 01 00		2007-09-21
Others	Doc C_052003.pdf				
Dengue					
OneStep Dengue Fever IgG&IgM RapiCard™ InstaTest (Serum /Whole Blood)	173106L-25	low risk	15 04 80 11 00		2003-11-12
OneStep Dengue Fever IgG/IgM RapiCard™ InstaTest (Cassette Serum Test)	173104-1	low risk	15 04 80 11 00		2003-11-12
OneStep Dengue Fever IgG RapiCard™ InstaTest (Cassette Serum Test)	173105-1	low risk	15 04 80 11 00		2003-11-12
OneStep Dengue Fever IgG RapiDip™ InstaTest (5mm Strip Serum Test)	173107-1	low risk	15 04 80 11 00		2003-11-12
OneStep Dengue Fever IgM RapiCard™ InstaTest (Cassette Serum Test)	175105-1	low risk	15 04 80 11 00		2003-11-12
OneStep Dengue Fever IgM RapiDip™ InstaTest (5mm Strip Serum Test)	175108-1	low risk	15 04 80 11 00		2003-11-12
One Step Dengue NS1 RapiDip™ InstaTest	173110-25	Low risk	15 70 90 90 00		2012-06-26
<b>Malaria</b>	<b>Doc C_052003.pdf</b>				
OneStep Malaria (P.f./vivax) RapiCard InstaTest	172110-25	low risk	15 04 80 90 00		2003-11-12
OneStep Malaria (P.f./vivax) RapiDip InstaTest (New)	172111-25	low risk	15 04 80 90 00		2003-11-12
<b>S. typhus</b>					
OneStep S. typhus IgG RapiDip™ Instatest	146117-25	low risk	15 70 01 90 00		2011-12-20
OneStep S. typhus IgM RapiDip™ Instatest	146118-25	low risk	15 70 01 90 00		2011-12-20
<b>Fertility</b>					
OneStep FSH Urine RapiCard™ InstaTest	198220-1	low risk	12 70 05 01 00		2003-11-12
<b>Ovulation</b>	Doc C_052003.pdf				



**Device group:  
 RAPIDTEST**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep LH Ovulation Urine RapiCard™ InstaTest (6days Pack)	104110-6	low risk	12 70 05 04 00		2003-11-12
OneStep LH Ovulation Urine RapiCard™ InstaTest (6days Pack)	104110ST-6	Self Test	12 70 05 04 00	0088/11349 5/00087	2003-11-12
OneStep LH Ovulation Urine RapiCard™ InstaTest (10 days Pack)	104110-10	low risk	12 70 05 04 00		2003-11-12
OneStep LH Ovulation Urine RapiCard™ InstaTest (10 days Pack)	104110ST-10	Self Test	12 70 05 04 00	0088/11349 5/00087	2003-11-12
OneStep LH Urine RapiCard™ InstaTest (Cassette Test)	104110-1	low risk	12 70 05 04 00		2003-11-12
OneStep LH Midstream RapiCard™ InstaTest	104117-1	low risk	12 70 05 04 00		2003-11-12
OneStep LH Urine RapiDip™ InstaTest (3.5mm Strip)	104113-1	low risk	12 70 05 04 00		2003-11-12
OneStep LH Urine RapiDip™ InstaTest (5mm Strip)	104115-1	low risk	12 70 05 04 00		2003-11-12
OneStep LH Urine RapiDip™ InstaTest	104113ST-1 104115ST-1 104114ST-1	Self Test	12 70 05 04 00	0088/11349 5/00087	2005-05-19
OneStep LH Urine RapiCard™ InstaTest	104110ST-1	Self Test	12 70 05 04 00	0088/11349 5/00087	2005-05-19
OneStep LH Urine Midstream InstaTest	104117ST-1	Self Test	12 70 05 04 00	0088/11349 5/00087	2005-05-19
<b>Pregnancy</b>	Doc C_052003.pdf				
OneStep HCG Midstream Urine RapiCard™ InstaTest	114360-1	low risk	12 70 05 02 00		2003-11-12
OneStep HCG Urine RapiCard™ InstaTest (Cassette)	113028-1	low risk	12 70 05 02 00		2003-11-12
OneStep HCG Urine RapiDip™ InstaTest (2.5mm Strip)	113042-1	low risk	12 70 05 02 00		2003-11-12
OneStep HCG Urine RapiDip™ InstaTest (3.5mm Strip)	113043-1	low risk	12 70 05 02 00		2003-11-12
OneStep HCG Urine RapiDip™ InstaTest (5mm Strip)	113045-1	low risk	12 70 05 02 00		2003-11-12
OneStep HCG Combo (Urine/Serum) RapiCard™ InstaTest (Cassette Test)	113029-1	low risk	12 70 05 02 00		2003-11-12
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest (3.5mm Strip)	113032-1	low risk	12 70 05 02 00		2003-11-12
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest (5mm Strip)	113030-1	low risk	12 70 05 02 00		2003-11-12

### Device group: RAPIDTEST



Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep HCG Urine RapiCard™ InstaTest	113028ST-1 113029ST-1	Self Test	12 70 05 02 00	0088/11349 5/00080	2004-10-20
OneStep HCG Urine Midstream InstaTest	114360ST-1	Self Test	12 70 05 02 00	0088/11349 5/00080	2004-10-20
OneStep HCG Urine RapiDip™ InstaTest	113042ST-1 113043ST-1 113045ST-1	Self Test	12 70 05 02 00	0088/11349 5/00080	2004-10-20
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest ( 3.5mm Strip)	113032ST-1	Self Test	12 70 05 02 00	0088/11349 5/00080	2008-06-01
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest ( 4 mm Strip)	113031ST-1	Self Test	12 70 05 02 00	0088/11349 5/00080	2008-06-01
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest ( 4 mm Strip)	113031-1	Low Risk	12 70 05 02 00		2008-06-01
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest ( 5 mm Strip)	113030-1	Low Risk	12 70 05 02 00		2008-06-01
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest ( 5 mm Strip)	113030ST-1	Self Test	12 70 05 02 00	0088/11349 5/00080	2008-06-01
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest ( 2.5 mm Strip)	113040-1	Low Risk	12 70 05 02 00		2008-06-01
OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest ( 2.5 mm Strip)	113040ST-1	Self Test	12 70 05 02 00	0088/11349 5/00080	2008-06-01
<b>Miscellaneous</b>	Doc C_052003.pdf				
OneStep Rheumatoid Factor RapiDip™ InstaTest(5mm Strip Serum Test)	145110-1	low risk	12 11 01 10 00		2003-11-12
OneStep Rheumatoid Factor RapiCard™ InstaTest, (Cassette Serum Test)	145112-1	low risk	12 11 01 10 00		2003-11-12
OneStep Rheumatoid Factor Serum/Whole Blood RapiCard™ InstaTest	145114-1	low risk	12 11 01 10 00		2003-11-12
OneStep Neonatal TSH Serum/Whole Blood RapiCard™ InstaTest	146116-1	low risk	12 04 01 03 00		2003-11-12
OneStep TSH Serum RapiDip™ InstaTest (5mm Strip Serum Test)	142110-1	low risk	12 04 01 11 00		2003-11-12
OneStep TSH RapiCard™ InstaTest, (Cassette Serum Test)	142112-1	low risk	12 04 01 11 00		2003-11-12
OneStep TSH Serum/whole Blood RapiCard™ InstaTest (Cassette Test)	142114-1	low risk	12 04 01 11 00		2003-11-12
OneStep Ferritin Serum RapiDip™ InstaTest (5mm Strip Serum Test)	140010-1	low risk	12 07 01 02 00		2003-11-12

### Device group: RAPIDTEST

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
OneStep Ferritin RapiCard™ InstaTest, (Cassette Serum Test)	140112-1	low risk	12 07 01 02 00		2003-11-12
OneStep Ferritin Serum/Whole Blood RapiCard™ InstaTest(Cassette Test)	140114-1	low risk	12 07 01 02 00		2003-11-12
<b>Urine Reagent Strips</b>	Doc C_052003.pdf				
URS-1B (Blood)	URS-1B	low risk	11 70 02 01 00		2003-11-12
URS-1G (Glucose)	URS-1G	low risk	11 70 02 01 00		2003-11-12
URS-1P (Protein)	URS-1P	low risk	11 70 02 01 00		2003-11-12
URS-1K (Ketone)	URS-1K	low risk	11 70 02 01 00		2003-11-12
URS-2K (Glucose/Ketone)	URS-2K	low risk	11 70 02 90 00		2003-11-12
URS-2P (Glucose/Protein)	URS-2P	low risk	11 70 02 90 00		2003-11-12
URS-3 (Glucose/Protein/pH)	URS-3	low risk	11 70 02 90 00		2003-11-12
URS-4B (Glucose/Protein/pH/Blood)	URS-4B	low risk	11 70 02 90 00		2003-11-12
URS-4S (Glucose/Protein/pH/SG)	URS-4S	low risk	11 70 02 90 00		2003-11-12
URS-5K (Blood/Ketone/Glucose/Protein/pH)	URS-5K	low risk	11 70 02 90 00		2003-11-12
URS-5U (Blood/Urobilinogen/Glucose/Protein/pH)	URS-5U	low risk	11 70 02 90 00		2003-11-12
URS-6 (Blood/Ketone/Glucose/Protein/pH/Bilirubin)	URS-6	low risk	11 70 02 90 00		2003-11-12
URS-6L (Blood/Ketone/Glucose/Protein/Leukocyte/Bilirubin)	URS-6L	low risk	11 70 02 90 00		2003-11-12
URS-7 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin)	URS-7	low risk	11 70 02 90 00		2003-11-12
URS-8 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin /Nitrite)	URS-8	low risk	11 70 02 90 00		2003-11-12
URS-9 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin /Nitrite /SG)	URS-9	low risk	11 70 02 90 00		2003-11-12



**Device group:  
RAPIDTEST**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
URS-10 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG /Leukocytes)	URS-10	low risk	11 70 02 90 00		2003-11-12
URS-11 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG /Leukocytes /Ascorbic Acid)	URS-11	low risk	11 70 02 90 00		2003-11-12

**Device group:  
Chemiluminescence Immuno Assay**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
<b>Thyroid Assays</b>					
	Doc D_112002.pdf				
T3	9001-16	low risk	12 04 01 05 00		2003-11-12
FT3	9002-15	low risk	12 04 01 01 00		2003-11-12
T4	9003-16	low risk	12 04 01 07 00		2003-11-12
FT4	9004-15	low risk	12 04 01 02 00		2003-11-12
TSH	9005-16	low risk	12 04 01 11 00		2003-11-12
T3 Uptake	9006-C	low risk	12 04 01 06 00		2003-11-12
Neonatal T4	9007-C	low risk	12 04 01 12 00		2003-11-12
<b>Autoimmune Thyroid Assays</b>					
Anti-Tg	9010-11	low risk	12 10 03 04 00		2003-11-12
Anti-TPO	9011-C	low risk	12 10 03 01 00		2003-11-12
<b>Fertility Assays</b>					
LH	9012-16	low risk	12 05 01 05 00		2003-11-12
FSH	9013-16	low risk	12 05 01 04 00		2003-11-12
PRL	9014-16	low risk	12 05 01 08 00		2003-11-12
hCG	9015-16	low risk	12 70 05 02 00		2003-11-12
<b>Growth Deficiency Assays</b>					
HGH	9020-16	low risk	12 06 04 02 00		2003-11-12
<b>Diabetes Assay</b>					
Insulin	9021-16	low risk	12 06 01 03 00		2003-11-12



**Device group:  
Chemiluminescence Immuno Assay**

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
C-peptide	9022-16	low risk	12 06 01 01 00		2003-11-12
Leptin	1742-6	low risk	12 06 90 17 00		2003-4-08
<b>Cardio-Vascular Monitoring Assay</b>					
CK-MB	9024-C	low risk	11 01 01 14 00		2003-11-12
<b>Cancer Marker Assay</b>					
AFP	9040-16	low risk	12 03 90 01 00		2003-11-12
CEA	9041-16	low risk	12 03 01 31 00		2003-11-12
Free Beta hCG	9043-16	low risk	12 05 02 90 00		2003-11-12
<b>Allergy Assays</b>					
IgE	9050-16	low risk	12 02 01 02 00		2003-11-12
<b>Others</b>					
Progesterone	9025-16	low risk	12 03 02 02 00		2003-11-12
Ferritin	9019-16	low risk	12 07 01 02 00		2013-12-19
CRP Latex Test Kit (Complete kit)	310-100	low risk	12 11 01 09 00		2008-06-01
RF Latex Test Kit (Complete kit)	320-100	low risk	12 11 01 10 00		2008-06-01
ASO Latex Test Kit (Complete kit)	330-50	low risk	12 11 01 05 00		2008-06-01
Mono Test Kit (Complete kit)	340-50	low risk	15 04 04 11 00		2008-06-01
RPR Test Kit (Complete kit)	500100-100	low risk	15 01 03 90 00		2008-06-01
RPR Test Kit (Complete kit)	500100-500	low risk	15 01 03 90 00		2008-06-01
SLE	351-50	low risk	12 10 01 16 00		2008-06-01

## Instruments

Device types	Document / page Catalog	Risk classification	EDMS code	CE- certificate	First CE-marking
Microplate Reader 2100	SF2100	low risk	21 01 10 01		15-10-2009
Microstrip Reader 303	SF303	low risk	21 01 10 01		4-2-2009
Microplate Reader 3200	SF3200	low risk	21 01 10 01		15-10-2009
LumiStat MicroStrip 4100	LUMI	low risk	21 01 10 01		4-2-2009
Microplate Washer 2600	SF2600	low risk	21 01 10 01		01-10-2003
Microwell Washer	SWASH	low risk	21 01 10 01		01-10-2003
Incubator/Shaker	SF2200	low risk	21 01 10 01		01-12-2003
Chemistry Analyzer 3300	SF3300	low risk	21 01 10 01		15-10- 2009
Chemistry Analyzer 1904	SF1904	low risk	21 01 10 01		01-12 2003
Urine Strip Reader 101	CD101	low risk	21 01 10 01		3-2008
Microplate reader DAR800	DAR800	low risk	21 01 01 00		2004-03-02
Microplate washer DAW50	DAW50	low risk	26 03 00 00		2004-03-02
Microplate Reader	SF4200	low risk	21 01 10 01		2013-12-19
Chemistry Analyzer	SF4500	low risk	21 01 10 01		2013-12-19
Microplate Reader	SF4700	low risk	21 01 10 01		2013-12-19