

Appendix A (Low Risk Devices)

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

Device types	Document / page ref. nr.:	Risk classification	EDMS code	CE-certificate	First CE-marking
Autoimmune Diseases and others:	Doc A_112002.pdf				
ANA Rat Liver IFA Kit	210906 - 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	22078	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	low risk	12 10 01 90 00		2003-11-12
ANA HEP-2 IFA Slide package	231096-SP	low risk	12 10 01 90 00		2003-11-12
AMA IFA Kit	240806	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	250608	low risk	12 10 90 90 00		2003-11-12
AAS Slide package	252508-SP	low risk	12 10 90 90 00		2003-11-12
ASMA IFA Kit	260806	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
ATA IFA Kit	270806	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
DNA IFA Kit	320608 – 321204	low risk	12 10 90 90 00		2003-11-12
DNA Slide package	322508-SP – 322504-SP	low risk	12 10 90 90 00		2003-11-12
Bacterial Diseases:	Doc A_112002.pdf				
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)	331008-6	low risk	15 01 05 03 00		2003-11-12

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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
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) 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 IgG/IgM IFA Kit	361010-G/M	low risk	15 01 06 03 00		2003-11-12
B.Burdoferi IgG IFA Kit	361010-G	low risk	15 01 06 05 00		2003-11-12
B.Burdoferi IgM IFA Kit	361010-M	low risk	15 01 06 06 00		2003-11-12
B.Burdoferi IgG Slides	362510-GSP	low risk	15 01 06 05 00		2003-11-12
B.Burdoferi IgM Slides	362510-MSP	low risk	15 01 06 06 00		2003-11-12
Viral diseases:					
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
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

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Varicella-Zoster Virus IgG IFA Kit / Slides	422510-GSP	low risk	15 04 80 10 00		2005-06-21
Parasitic Diseases:					
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
Trichinosis	431303-B60	low risk	15 05 10 90 00		2003-11-12

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Device group: Elisa Kits

Device types	Document / page ref. nr.:	Risk classification	EDMS code	CE-certificate	First CE-marking
Autoimmune Disease and others	Doc B_052003.pdf				
ANA Screen	5102	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	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	low risk	12 10 01 02 00		2003-11-12
Sm/RNP	2558-1	low risk	12 10 01 11 00		2003-11-12
Sm	2557-1	low risk	12 10 01 11 00		2003-11-12
Jo-1	2570-1	low risk	12 10 01 08 00		2003-11-12
Scl-70	2559-1	low risk	12 10 01 10 00		2003-11-12
SS-A (Ro)	2555-1	low risk	12 10 01 12 00		2003-11-12
SS-B (La)	2556-1	low risk	12 10 01 13 00		2003-11-12
dsDNA	2553	low risk	12 10 01 05 00		2003-11-12
Cardiolipin IgG	1491	low risk	12 10 01 90 00		2003-11-12
Cardiolipin IgM	1492	low risk	12 10 01 90 00		2003-11-12
Cardiolipin IgA	1493	low risk	12 10 01 90 00		2003-11-12
Cardiolipin IgG, A, M	1490	low risk	12 10 01 90 00		2003-11-12
Histone	2571	low risk	12 10 01 07 00		2003-11-12
Rheumatoid Factor (RF)	2550	low risk	12 11 01 10 00		2003-11-12
Mitochondria	1420	low risk	12 10 90 02 00		2003-11-12
Thyroglobulin	1421	low risk	12 04 01 08 00		2003-11-12
Thyroid Microsomal	1422	low risk	12 10 03 01 00		2003-11-12
Ribosomal P	1431	low risk	12 10 90 20 00		2003-11-12
PR3 (c-ANCA)	1445	low risk	12 10 90 10 00		2003-11-12
ANCA screen IgG	1681	low risk	12 10 01 90 00		2003-11-12
MPO ,Myeloperoxidase (p-ANCA)	1441	low risk	12 10 90 09 00		2003-11-12
Gliadin IgG	1021	low risk	12 10 90 06 00		2003-11-12
Gliadin IgA	1022	low risk	12 10 90 06 00		2003-11-12
Cancer (tumor markers)	Doc B_052003.pdf				
Prostatic Acid Phosphatase (PAP)	4227	low risk	12 03 01 37 00		2003-11-12

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b2-Microglobulin	4200	low risk	12 03 90 02 00		2003-11-12
AFP (Alpha Fetoprotein)	5101	low risk	12 03 90 01 00		2003-11-12
CEA	5201	low risk	12 03 01 31 00		2003-11-12
CA-15-3	6333	low risk	12 03 01 02 00		2003-11-12
CA-12-5	6502	low risk	12 03 01 06 00		2003-11-12
CA-19-9	6909	low risk	12 03 01 03 00		2003-11-12
CA-242	6335	low risk	12 03 01 08 00		2003-11-12
NSE	6334	low risk	12 03 90 08 00		2003-11-12
Ferritin	1601	low risk	12 07 01 02 00		2003-11-12
Free Beta HCG	4221	low risk	12 03 01 90 00		2003-11-12
Cardiac	Doc B_052003.pdf				2003-11-12
CK-MB	1005	low risk	11 01 01 14 00		2003-11-12
Troponin I	1105	low risk	12 70 13 03 00		2003-11-12
Myoglobin	1667	low risk	12 13 01 05 00		2003-11-12
C-Reactive Protein (CRP)	1668	low risk	12 11 01 09 00		2003-11-12
OLAB	2032-7	low risk	12 13 01 90 00		2003-11-12
Endothelin	2052-7	low risk	12 13 01 90 00		2003-11-12
MGP	2062-7	low risk	12 13 01 90 00		2003-11-12
Big ET	2072-7	low risk	12 13 01 90 00		2003-11-12
Pro-ANP(1098)	2892-7	low risk	12 13 01 01 00		2003-11-12
Nt-proBNP	2852-7	low risk	12 13 01 90 00		2003-11-12
OxyStat	5007-7	low risk	12 13 01 90 00		2003-11-12
Allergy	Doc B_052003.pdf				
Total Human IgE	1801	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
Human Specific IgE	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
Bone Metabolism	Doc B_052003.pdf				
Intact PTH	1735	low risk	12 06 03 13 00		2003-11-12
125 Dihydroxyvitamin D	1737	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

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Fertility (Reproduction Function)	Doc B_052003.pdf				
Human Growth Hormone (HGH)	1901	low risk	12 06 04 02 00		2003-11-12
hCG	4223	low risk	12 05 02 05 00		2003-11-12
Beta hCG	4201	low risk	12 05 02 06 00		2003-11-12
FSH	4224	low risk	12 05 01 04 00		2003-11-12
LH	4225	low risk	12 05 01 05 00		2003-11-12
Prolactin (PRL)	4226	low risk	12 05 01 08 00		2005-06-21
Steroid	Doc B_052003.pdf				
Cortisol	6101	low risk	12 06 02 04 00		2003-11-12
Estradiol	2046	low risk	12 05 01 03 00		2003-11-12
DHEA-S	2055	low risk	12 05 01 02 00		2003-11-12
DHEA	2056	low risk	12 05 01 02 00		2003-11-12
Progesterone	2077	low risk	12 05 01 06 00		2003-11-12
Testosterone	2095	low risk	12 05 01 10 00		2003-11-12
Free Testosterone	2924	low risk	12 05 01 10 00		2003-11-12
Androstenedione (ASD)	1038	low risk	12 05 01 01 00		2003-11-12
Estriol	3171	low risk	12 05 02 02 00		2003-11-12
17-alpha hydroxy Progesterone	1292	low risk	12 06 05 04 00		2005-06-21
Thyroid	Doc B_052003.pdf				
T3	3144	low risk	12 04 01 05 00		2003-11-12
T4	3149	low risk	12 04 01 07 00		2003-11-12
TSH	3122	low risk	12 04 01 11 00		2003-11-12
Free T4	3146	low risk	12 04 01 02 00		2003-11-12
Free T3	3148	low risk	12 04 01 01 00		2003-11-12
T Uptake	3176	low risk	12 04 01 06 00		2003-11-12
NNT4 (NeoNatal T4)	3150	low risk	12 04 01 12 00		2003-11-12
Infectious Diseases	Doc B_052003.pdf				
Adenovirus IgA	5101-8	low risk	15 04 80 01 00		2003-11-12
Adenovirus IgG	5102-8	low risk	15 04 80 01 00		2003-11-12
Adenovirus IgM	5103-8	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

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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	low risk	15 04 03 08 00		2003-11-12
Herpes Simplex 1 IgM (HSV1 IgM)	1402	low risk	15 04 03 09 00		2003-11-12
Herpes Simplex 2 IgG (HSV2 IgG)	1403	low risk	15 04 03 11 00		2003-11-12
Herpes Simplex 2 IgM (HSV2 IgM)	1404	low risk	15 04 03 12 00		2003-11-12
Herpes Simplex 1,2 IgG (HSV1,2 IgG)	1443	low risk	15 04 03 90 00		2003-11-12
Herpes Simplex 1,2 IgM (HSV1,2 IgM)	1444	low risk	15 04 03 90 00		2003-11-12
Epstein Barr Virus VCA IgG (EBV, VCA IgG)	1405	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus VCA IgM (EBV, VCA IgM)	1406	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus Early Antigen (EA) IgG	1415	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus Nuclear Antigen (EBNA) IgG	1425	low risk	15 04 04 90 00		2003-11-12
Epstein Barr Virus Nuclear Antigen (EBNA) IgM	1426	low risk	15 04 04 90 00		2003-11-12
Measles IgG	1408	low risk	15 04 80 07 00		2003-11-12
Measles IgM	1409	low risk	15 04 80 07 00		2003-11-12
Mumps IgG	1410	low risk	15 04 80 08 00		2003-11-12
Mumps IgM	1411	low risk	15 04 80 08 00		2003-11-12
Mycoplasma pneumonia IgG	8042	low risk	15 01 08 90 00		2003-11-12
Mycoplasma pneumonia IgM	8043	low risk	15 01 08 90 00		2003-11-12
Syphilis (TPA) IgG	1463	low risk	15 01 03 05 00		2003-11-12
Syphilis (TPA) IgM	1464	low risk	15 01 03 06 00		2003-11-12
Legionella G/M/A	1651	low risk	15 01 05 01 00		2003-11-12
H.pylori IgG	1503	low risk	15 01 04 01 00		2003-11-12

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H.pylori IgA	1505	low risk	15 01 04 01 00		2003-11-12
H-Pylori IgM	1504	low risk	15 01 04 01 00		2003-11-12
Varicella-Zoster IgG	1412	low risk	15 04 80 10 00		2003-11-12
Varicella-Zoster IgM	1413	low risk	15 04 80 10 00		2003-11-12
Brucella IgG	1501	low risk	15 01 90 01 00		2003-11-12
Brucella IgM	1502	low risk	15 01 90 01 00		2003-11-12
HEV IgM	1876	low risk	15 02 05 06 00		2003-11-12
HEV Ab	1877	low risk	15 02 05 04 00		2003-11-12
HGV Ab	1887	low risk	15 02 07 04 00		2003-11-12
HAV IgM	1518	low risk	15 02 01 06 00		2003-11-12
Parasitology Antibody Detection	Doc B_052003.pdf				
Schistosoma	8209-3	low risk	15 05 10 06 00		2003-11-12
Chagas	8100-3	low risk	15 05 10 02 00		2003-11-12
Cysticercosis (T. Solium)	8105-3	low risk	15 05 10 90 00		2003-11-12
Dengue IgG/IgM	8115-3	low risk	15 04 80 11 00		2003-11-12
Dengue IgG	8116-3	low risk	15 04 80 11 00		2003-11-12
Dengue IgM	8117-3	low risk	15 04 80 11 00		2003-11-12
Diphtheria	8118-3	low risk	15 05 10 90 00		2003-11-12
E. Histolytica (Amebiasis)	8201-3	low risk	15 05 10 90 00		2003-11-12
Echinococcus	8202-3	low risk	15 05 10 04 00		2003-11-12
Leishmania	8203-3	low risk	15 05 10 05 00		2003-11-12
Leptospira IgG	8204-3	low risk	15 01 90 04 00		2003-11-12
Leptospira IgM	8208-3	low risk	15 01 90 04 00		2003-11-12
Tetanus	8205-3	low risk	15 01 90 09 00		2003-11-12
Toxocara	8206-3	low risk	15 05 10 90 00		2003-11-12
Trichinella	8207-3	low risk	15 05 10 90 00		2003-11-12
Parasitology Antigen detection	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
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

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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
Diabetes	Doc B_052003.pdf				
Insulin	1606	low risk	12 06 01 03 00		2003-11-12
C-peptide	1293	low risk	12 06 01 01 00		2003-11-12
Others	Doc B_052003.pdf				
Histamine	1738-8	low risk	12 02 01 01 00		2003-11-12
Vitamin H (Biotin)	1737-8	low risk	12 07 02 90 00		2003-11-12
Vitamin B12	1739-8	low risk	12 07 02 04 00		2003-11-12
Folate (Folic Acid)	1736-8	low risk	12 07 01 03 00		2003-11-12
Lp(a)	1740-9	low risk	12 01 04 21 00		2003-11-12
Anti-Tetanus Toxoid	9800	low risk	15 01 90 09 00		2005-06-21
Diphtheria Toxoid IgG	1760	low risk	15 04 80 90 00		2003-11-12

Device group: Rapid Test products

Device types	Document / page ref. nr.:	Risk classification	EDMS code	CE-certificate	First CE-marking
Allergy	Doc C_052003.pdf				2003-11-12
OneStep IgE Serum RapiCard™ InstaTest	15150-1	low risk	12 02 01 02 00		2003-11-12
Cancer	Doc C_052003.pdf				
Hemo Fecal Occult		low risk	12 03 90 04 00		2003-11-12
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
CEA	Doc C_052003.pdf	low risk			

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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
AFP	Doc C_052003.pdf	low risk			2003-11-12
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
AFP Serum (Uncut Sheet, Strip)	13041-SHU	low risk	12 03 90 01 00		2003-11-12
Cardiac markers	Doc C_052003.pdf	low risk			
C-Reactive Protein (CRP) Serum RapiCard™ InstaTest	166770-1	low risk	12 70 11 01 00		2003-11-12
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)	166775-1	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	166779-1	low risk	12 70 13 90 00		2003-11-12

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I/Myoglobin/CK-MB (Serum/Whole Blood RapiCard InstaTest)					
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
Drug Test	Doc C_052003.pdf				
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 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	121070-1	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	121039-1	low risk	12 70 09 90 00		2003-11-12

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RapiCard™ InstaTest ,(MAD, COR,THC,AMP,COC,BZD)					
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
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	121071-1	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 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)	121073-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest, (AMP,BAR,BZD,COC,MOR,	121081-1	low risk	12 70 09 90 00		2003-11-12

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THC)					
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,THC)	120620-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ InstaTest,(BAR,BZD,COC,M AD,MOR,THC)	120625-1	low risk	12 70 09 90 00		2003-11-12
OneStep 6-Drug RapiDip™ nstaTest,(AMP,BZD,COC,M ET,MAD,MOR)	120630-1	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™	120520-1	low risk	12 70 09 90 00		2003-11-12

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InstaTest, (BZD,MET,MOR,PCP,THC)					
OneStep 5-Drug RapiDip™ InstaTest, (AMP,BZD,COC,MOR,THC)	120535-1	low risk	12 70 09 90 00		2003-11-12
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)	121056-1	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)	120310-1	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

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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
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)	120250-1	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 Ceck NoStep RapiCup	Doc C_052003.pdf	low risk			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
Infectious Diseases and others	Doc C_052003.pdf				
Chagas		low risk	15 05 10 02 00		2003-11-12
Chagas Two Spot RapiDip™ InstaTest (Serum/Plasma Test)	174105-1	low risk	15 05 10 02 00		2003-11-12
OneStep Gonorrhea RapiCard™ InstaTest (Cassette Swab Test)	176510-25	low risk	15 05 10 90 00		2003-11-12
OneStep Gonorrhea RapiDip™ InstaTest (5mm Strip Swab Test)	176512-25	low risk	15 05 10 90 00		2003-11-12
Leishmania		low risk	15 05 10 05 00		2003-11-12
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
OneStep Syphilis RapiCard™ InstaTest (Cassette Serum Test)	176500-25	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
Mono	Doc C_052003.pdf	low risk			2003-11-12
OneStep Mononucleosis RapiCard™ InstaTest	176522-1	low risk	15 70 90 03 00		2003-11-12

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(Cassette Serum Test)					
Strep A		low risk			2003-11-12
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
H. Pylori					
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
Others	Doc C_052003.pdf				
Dengue					
OneStep Dengue Fever IgG&IgM RapiCard™ InstaTest (Serum /Whole Blood) Separate IgG AND igM	173106-1	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
Malaria	Doc C_052003.pdf				
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
Fertility					
OneStep FSH Urine RapiCard™ InstaTest	198220-1	low risk	12 70 05 01 00		2003-11-12

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OneStep FSH Urine RapiCard™ InstaTest	198220ST-1	Self-testing	12 70 05 01 00	0088/11349 5/00082	2005-01-06
OneStep FSH Urine RapiDip™ InstaTest	198219ST-1	Self-testing	12 70 05 01 00	0088/11349 5/00082	2005-01-06
Ovulation	Doc C_052003.pdf				
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 (10 days Pack)	104110-10	low risk	12 70 05 04 00		2003-11-12
OneStep LH Urine RapiCard™ InstaTest (Cassette Test)	104116-1	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	Self-Testing	12 70 05 04 00	0088/11349 5/00087	2005-05-19
OneStep LH Urine RapiCard™ InstaTest	104116ST-1	Self-Testing	12 70 05 04 00	0088/11349 5/00087	2005-05-19
OneStep LH Urine Midstream InstaTest	104117ST-1	Self-Testing	12 70 05 04 00	0088/11349 5/00087	2005-05-19
Pregnancy	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)	113046-1	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™	113030-1	low risk	12 70 05 02 00		2003-11-12

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InstaTest (5mm Strip)					
OneStep HCG Urine RapiCard™ InstaTest	113028ST-1 113029ST-1	Self-Testing	12 70 05 02 00	0088/11349 5/00080	2004-10-20
OneStep HCG Urine Midstream InstaTest	114360SR-1	Self-Testing	12 70 05 02 00	0088/11349 5/00080	2004-10-20
OneStep HCG Urine RapiDip™ InstaTest	113042ST-1 113046ST-1 113045ST-1	Self-Testing	12 70 05 02 00	0088/11349 5/00080	2004-10-20
Miscellaneous	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
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
Urine Reagent Strips	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-1G	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	URS-34B	low risk	11 70 02 90 00		2003-11-12

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(Glucose/Protein/pH/Blood)					
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
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 ImmunoAssays

Device types	Document / page ref. nr.:	Risk classification	EDMS Code	CE-certificate	First CE-marking
Thyroid Assays	Doc D_112002.pdf				
T3	9001-C	low risk	12 04 01 05 00		2003-11-12
FT3	9002-C	low risk	12 04 01 01 00		2003-11-12
T4	9003-C	low risk	12 04 01 07 00		2003-11-12
FT4	9004-C	low risk	12 04 01 02 00		2003-11-12

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TSH	9005-C	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
Autoimmune Thyroid Assays					
Anti-Tg	9010-C	low risk	12 10 03 04 00		2003-11-12
Anti-TPO	9011-C	low risk	12 10 03 01 00		2003-11-12
Fertility Assays					
LH	9012-C	low risk	12 05 01 05 00		2003-11-12
FSH	9013-C	low risk	12 05 01 04 00		2003-11-12
PRL	9014-C	low risk	12 05 01 08 00		2003-11-12
hCG	9015-C	low risk	12 70 05 02 00		2003-11-12
Growth Deficiency Assays					
HGH	9020-C	low risk	12 06 04 02 00		2003-11-12
Diabetes Assay					
Insulin	9021-C	low risk	12 06 01 03 00		2003-11-12
C-peptide	9022-C	low risk	12 06 01 01 00		2003-11-12
Cardio-Vascular Monitoring Assay					
CK-MB	9024-C	low risk	11 01 01 14 00		2003-11-12
Cancer Marker Assay					
AFP	9040-C	low risk	12 03 90 01 00		2003-11-12
CEA	9041-C	low risk	12 03 01 31 00		2003-11-12
Free Beta hCG	9043-C	low risk	12 05 02 90 00		2003-11-12
Allergy Assays					
IgE	9050-C	low risk	12 02 01 02 00		2003-11-12
Others					
Feritin	9019-C	low risk			2003-11-12
Progesterone	9025-C	low risk	12 03 02 02 00		2003-11-12