

104067_SSL	Drug-Screen® Multi 6TI Test
104068	Drug-Screen® Multi 6TJ Test
104069	Drug-Screen® Multi 6TK Test
104070	Drug-Screen® Multi 7TA Test
104070N-10	Drug-Screen® Multi 7TA Test
104070N-10_SSL	Drug-Screen® Multi 7TA Test
104071	Drug-Screen® Multi 7TB Test
104072	Drug-Screen® Multi 7TC Test
104072_SSL	Drug-Screen® Multi 7TC Test
104072N-10	Drug-Screen® Multi 7TC Test
104073	Drug-Screen® Multi 7TD Test
104074	Drug-Screen® Multi 7TE Test
104075	Drug-Screen® Multi 7TF Test
104075P	Multi 7TF Test
104076	Drug-Screen® Multi 7TG Test
104076_SSL	Drug-Screen® Multi 7TG Test
104077	Drug-Screen® Multi 7TH Test
104078	Drug-Screen® Multi 7TJ Test
104079	Drug-Screen® Multi 7TL Test
104080	Drug-Screen® Multi 8TA Test
104081	Drug-Screen® Multi 8TB Test
104082	Drug-Screen® Multi 8TC Test
104082_SSL	Drug-Screen® Multi 8TC Test
104082N-10	Drug-Screen® Multi 8TC Test
104082P	Multi 8TC Test
104084	Drug-Screen® Multi 8TD Test
104085	Drug-Screen® Multi 8TE Test
104085_SSL	Drug-Screen® Multi 8TE Test
104086	Drug-Screen® Multi 8TF Test
104087	Drug-Screen® Multi 8TG Test
104088	Drug-Screen® Multi 8TH Test
104089	Drug-Screen® Multi 8TJ Test
104090	Drug-Screen® Multi 9TA Test
104091	Drug-Screen® Multi 9TB Test
104092	Drug-Screen® Multi 9TC Test
104092BA	Drug-Screen® Multi 9TC Barcoded Test
104092BA_SSL	Drug-Screen® Multi 9TC Barcoded Test
104092P	Multi 9TC Test
104092PBA	Multi 9TC Barcoded Test

104093BA	Drug-Screen® Multi 9TD Barcoded Test
104093BA_SSL	Drug-Screen® Multi 9TD Barcoded Test
104094	Drug-Screen® Multi 8TL-AC-A Test
104095	Drug-Screen® Multi 9TF Test
104095_SSL	Drug-Screen® Multi 9TF Test
104096	Drug-Screen® Multi 9TG Test
104097	Drug-Screen® Multi 9TH Test
104100	Drug-Screen® Multi 10TC Test
104100N-10	Drug-Screen® Multi 10TC Test
104100P	Multi 10TC Test
104101	Drug-Screen® Multi 10TD Test
104101BA	Drug-Screen® Multi 10TD Barcoded Test
104101N-10	Drug-Screen® Multi 10TD Test
104101N-10_SSL	Drug-Screen® Multi 10TD Test
104101P	Multi 10TD Test
104101PBA	Multi 10TD Barcoded Test
104105	Drug-Screen® Multi 10TE Test
104105_SSL	Drug-Screen® Multi 10TE Test
104105P	Multi 10TE Test
104105P_SSL	Multi 10TE Test
104106	Drug-Screen® Multi 10TF Test
104106_SSL	Drug-Screen® Multi 10TF Test
104107	Drug-Screen® Multi 10TC-AC-C Test
104108	Drug-Screen® Multi 10TH Test
104108_SSL	Drug-Screen® Multi 10TH Test
104109	Drug-Screen® Multi 10TG Test
104109_SSL	Drug-Screen® Multi 10TG Test
104110	Drug-Screen® Multi 11TA Test
104110BA	Drug-Screen® Multi 11TA Barcoded Test
104111	Drug-Screen® Multi 11TB Test
104111_SSL	Drug-Screen® Multi 11TB Test
104112	Drug-Screen® Multi 11TC Test
104112_SSL	Drug-Screen® Multi 11TC Test
104114	Drug-Screen® Multi 11TE Test
104114_SSL	Drug-Screen® Multi 11TE Test
104116	Drug-Screen® Multi 11TH Test
104117	Drug-Screen® Multi 10TI Test
104118	Drug-Screen® Multi 10TJ Test

EC-Declaration of Conformity

new art laboratories



Page 13 of 22

104067_SSL	Drug-Screen® Multi 6TI Test
104068	Drug-Screen® Multi 6TJ Test
104069	Drug-Screen® Multi 6TK Test
104070	Drug-Screen® Multi 7TA Test
104070N-10	Drug-Screen® Multi 7TA Test
104070N-10_SSL	Drug-Screen® Multi 7TA Test
104071	Drug-Screen® Multi 7TB Test
104072	Drug-Screen® Multi 7TC Test
104072_SSL	Drug-Screen® Multi 7TC Test
104072N-10	Drug-Screen® Multi 7TC Test
104073	Drug-Screen® Multi 7TD Test
104074	Drug-Screen® Multi 7TE Test
104075	Drug-Screen® Multi 7TF Test
104075P	Multi 7TF Test
104076	Drug-Screen® Multi 7TG Test
104076_SSL	Drug-Screen® Multi 7TG Test
104077	Drug-Screen® Multi 7TH Test
104078	Drug-Screen® Multi 7TJ Test
104079	Drug-Screen® Multi 7TL Test
104080	Drug-Screen® Multi 8TA Test
104081	Drug-Screen® Multi 8TB Test
104082	Drug-Screen® Multi 8TC Test
104082_SSL	Drug-Screen® Multi 8TC Test
104082N-10	Drug-Screen® Multi 8TC Test
104082P	Multi 8TC Test
104084	Drug-Screen® Multi 8TD Test
104085	Drug-Screen® Multi 8TE Test
104085_SSL	Drug-Screen® Multi 8TE Test
104086	Drug-Screen® Multi 8TF Test
104087	Drug-Screen® Multi 8TG Test
104088	Drug-Screen® Multi 8TH Test
104089	Drug-Screen® Multi 8TJ Test
104090	Drug-Screen® Multi 9TA Test
104091	Drug-Screen® Multi 9TB Test
104092	Drug-Screen® Multi 9TC Test
104092BA	Drug-Screen® Multi 9TC Barcoded Test
104092BA_SSL	Drug-Screen® Multi 9TC Barcoded Test
104092P	Multi 9TC Test
104092PBA	Multi 9TC Barcoded Test

104093BA	Drug-Screen® Multi 9TD Barcoded Test
104093BA_SSL	Drug-Screen® Multi 9TD Barcoded Test
104094	Drug-Screen® Multi 8TL-AC-A Test
104095	Drug-Screen® Multi 9TF Test
104095_SSL	Drug-Screen® Multi 9TF Test
104096	Drug-Screen® Multi 9TG Test
104097	Drug-Screen® Multi 9TH Test
104100	Drug-Screen® Multi 10TC Test
104100N-10	Drug-Screen® Multi 10TC Test
104100P	Multi 10TC Test
104101	Drug-Screen® Multi 10TD Test
104101BA	Drug-Screen® Multi 10TD Barcoded Test
104101N-10	Drug-Screen® Multi 10TD Test
104101N-10_SSL	Drug-Screen® Multi 10TD Test
104101P	Multi 10TD Test
104101PBA	Multi 10TD Barcoded Test
104105	Drug-Screen® Multi 10TE Test
104105_SSL	Drug-Screen® Multi 10TE Test
104105P	Multi 10TE Test
104105P_SSL	Multi 10TE Test
104106	Drug-Screen® Multi 10TF Test
104106_SSL	Drug-Screen® Multi 10TF Test
104107	Drug-Screen® Multi 10TC-AC-C Test
104108	Drug-Screen® Multi 10TH Test
104108_SSL	Drug-Screen® Multi 10TH Test
104109	Drug-Screen® Multi 10TG Test
104109_SSL	Drug-Screen® Multi 10TG Test
104110	Drug-Screen® Multi 11TA Test
104110BA	Drug-Screen® Multi 11TA Barcoded Test
104111	Drug-Screen® Multi 11TB Test
104111_SSL	Drug-Screen® Multi 11TB Test
104112	Drug-Screen® Multi 11TC Test
104112_SSL	Drug-Screen® Multi 11TC Test
104114	Drug-Screen® Multi 11TE Test
104114_SSL	Drug-Screen® Multi 11TE Test
104116	Drug-Screen® Multi 11TH Test
104117	Drug-Screen® Multi 10TI Test
104118	Drug-Screen® Multi 10TJ Test

104119	Drug-Screen® Multi 11TI Test
104120	Drug-Screen® Multi 12T Test
104120_SSL	Drug-Screen® Multi 12T Test
104120BA	Drug-Screen® Multi 12T Barcoded Test
104120BA_SSL	Drug-Screen® Multi 12T Barcoded Test
104120P	Multi 12T Test
104121	Drug-Screen® Multi 12TA Test
104122	Drug-Screen® Multi 12TB Test
104122_SSL	Drug-Screen® Multi 12TB Test
104123	Drug-Screen® Multi 12TC Test
104123BA	Drug-Screen® Multi 12TC Barcoded Test
104123N-10	Drug-Screen® Multi 12TC Test
104123P	Multi 12TC Test
104123P_SSL	Multi 12TC Test
104124	Drug-Screen® Multi 12TD Test
104125	Drug-Screen® Multi 12TE Test
104125_SSL	Drug-Screen® Multi 12TE Test
104125BA	Drug-Screen® Multi 12TE Barcoded Test
104126	Drug-Screen® Multi 12TF Test
104126_SSL	Drug-Screen® Multi 12TF Test
104127	Drug-Screen® Multi 12TG Test
104127_SSL	Drug-Screen® Multi 12TG Test
104128	Drug-Screen® Multi 12TH Test
104130	Drug-Screen® Multi 3TK Test
104131	Drug-Screen® Multi 3TL Test
104132	Drug-Screen® Multi 3TM Test
104132_SSL	Drug-Screen® Multi 3TM Test
104133	Drug-Screen® Multi 3TN Test
104133_SSL	Drug-Screen® Multi 3TN Test
104134	Drug-Screen® Multi 3TP Test
104135	Drug-Screen® Multi 3TQ Test
104135_SSL	Drug-Screen® Multi 3TQ Test
104136	Drug-Screen® Multi 3TR Test
104136_SSL	Drug-Screen® Multi 3TR Test
104137	Drug-Screen® Multi 3TS Test
104137_SSL	Drug-Screen® Multi 3TS Test
104138	Drug-Screen® Multi 3TT Test
104139	Drug-Screen® Multi 3TU Test
104140	Drug-Screen® Multi 3TV Test

104150	Drug-Screen® Multi 5TA Test
104151	Drug-Screen® Multi 5TB Test
104152	Drug-Screen® Multi 5TC Test
104152_SSL	Drug-Screen® Multi 5TC Test
104153	Drug-Screen® Multi 5TP Test
104154	Drug-Screen® Multi 5TR Test
104155	Drug-Screen® Multi 5TS Test
104156	Drug-Screen® Multi 2TD Test
104156_SSL	Drug-Screen® Multi 2TD Test
104157	Drug-Screen® Multi 5TU Test
104157_SSL	Drug-Screen® Multi 5TU Test
104158	Drug-Screen® Multi 5TV Test
104158_SSL	Drug-Screen® Multi 5TV Test
104159	Drug-Screen® Multi 5TW Test
104159_SSL	Drug-Screen® Multi 5TW Test
104160	Drug-Screen® Multi 6TL Test
104161	Drug-Screen® Multi 6TM Test
104162	Drug-Screen® Multi 6TN Test
104163	Drug-Screen® Multi 6TP Test
104163_SSL	Drug-Screen® Multi 6TP Test
104164	Drug-Screen® Multi 6TR Test
104165	Drug-Screen® Multi 6TS Test
104165_SSL	Drug-Screen® Multi 6TS Test
104166	Drug-Screen® Multi 5TX Test
104167	Drug-Screen® Multi 6TT Test
104168	Drug-Screen® Multi 6TU Test
104168_SSL	Drug-Screen® Multi 6TU Test
104169	Drug-Screen® Multi 6TV Test
104169_SSL	Drug-Screen® Multi 6TV Test
104170	Drug-Screen® Multi 7TK Test
104170_SSL	Drug-Screen® Multi 7TK Test
104171	Drug-Screen® Multi 7TM Test
104171_SSL	Drug-Screen® Multi 7TM Test
104172	Drug-Screen® Multi 7TN Test
104172N-10	Drug-Screen® Multi 7TN Test
104173	Drug-Screen® Multi 7TO Test
104174	Drug-Screen® Multi 7TP Test
104175	Drug-Screen® Multi 7TR Test
104175N-25	Drug-Screen® Multi 7TR Test
104175N-25_SSL	Drug-Screen® Multi 7TR Test

104176	Drug-Screen® Multi 7TS Test
104176_SSL	Drug-Screen® Multi 7TS Test
104177	Drug-Screen® Multi 7TT Test
104178	Drug-Screen® Multi 7TU Test
104179	Drug-Screen® Multi 7TV-AC-A Test
104180	Drug-Screen® Multi 8TK Test
104181	Drug-Screen® Multi 8TM Test
104181_SSL	Drug-Screen® Multi 8TM Test
104182	Drug-Screen® Multi 8TN Test
104182_SSL	Drug-Screen® Multi 8TN Test
104183	Drug-Screen® Multi 8TO Test
104184	Drug-Screen® Multi 8TP Test
104185	Drug-Screen® Multi 8TQ Test
104185BA	Drug-Screen® Multi 8TQ Barcoded Test
104186	Drug-Screen® Multi 8TR Test
104187	Drug-Screen® Multi 8TS Test
104210	Drug-Screen® Multi 11TJ Test
104211	Drug-Screen® Multi 11TK-AC-C Test
104213	Drug-Screen® Multi 11TM Test
104214	Drug-Screen® Multi 11TN Test
104214BA	Drug-Screen® Multi 11TN Barcoded Test
104215	Drug-Screen® Multi 10TQ Test
104216BA	Drug-Screen® Multi 11TO Barcoded Test
104230	Drug-Screen® Multi 3TW Test
104231P	Multi 3TX Test
104232	Drug-Screen® Multi 3TY Test
104233	Drug-Screen® Multi 3TZ Test
104250	Drug-Screen® Multi 5TY Test
104250_SSL	Drug-Screen® Multi 5TY Test
104251	Drug-Screen® Multi 5TZ Test
104252	Drug-Screen® Multi 5TAA Test
104255	Drug-Screen® Multi 5TAD Test
104256	Drug-Screen® Multi 5TAE Test
104257	Drug-Screen® Multi 5TAF Test
104258P	Multi 5TAG Test
104260	Drug-Screen® Multi 6TW Test
104261	Drug-Screen® Multi 6TX Test
104261_SSL	Drug-Screen® Multi 6TX Test
104262	Drug-Screen® Multi 6TY Test

104263	Drug-Screen® Multi 6TZ Test
104263_SSL	Drug-Screen® Multi 6TZ Test
104263N-10	Drug-Screen® Multi 6TZ Test
104263N-10-1	Drug-Screen® Multi 6TZ Test
104263N-10-2	Drug-Screen® Multi 6TZ Test
104270	Drug-Screen® Multi 7TW Test
104310	Drug-Screen® Multi 10TL Test
104311	Drug-Screen® Multi 10TM Test
104312	Drug-Screen® Multi 10TN Test
104313	Drug-Screen® Multi 10TO Test
104314	Drug-Screen® Multi 10TP Test
104315BA	Drug-Screen® Multi 10TR Barcoded Test
104315NBA-10	Drug-Screen® Multi 10TR Barcoded Test
104316	Drug-Screen® Multi 10TS Test
105030	Drug-Screen® MQL 300 ng/mL Test
105030_SSL	Drug-Screen® MQL 300 ng/mL Test
105031	Drug-Screen® BZD 100 ng/mL Test
105032	Drug-Screen® OXY 100 ng/mL Test
105034	Drug-Screen® PCM 5000 ng/mL Test
105038	Drug-Screen® THC 300 ng/mL Test
105039	Drug-Screen® THC 500 ng/mL Test
105045	Drug-Screen® Spice50 Test
105047	Drug-Screen® TZD 25 ng/mL Test
105049	Drug-Screen® ZAL 100 ng/mL Test
105049_SSL	Drug-Screen® ZAL 100 ng/mL Test
105054	Drug-Screen® COT 50 ng/mL Test
105055	Drug-Screen® COT 1000 ng/mL Test
105059	Drug-Screen® EtG 1000 ng/mL Test
105061	Drug-Screen® BUP 5 ng/mL Test
105062	Drug-Screen® EtG 500 ng/mL Test
105064	Drug-Screen® COC 600 ng/mL Test
105067	Drug-Screen® PBG 500 ng/mL Test
105070	Drug-Screen® ZOL 25 ng/mL Test
105071	Drug-Screen® TIL 300 ng/mL Test
105076	Drug-Screen® MDPV 500 ng/mL Test
105078	Drug-Screen® MPD 150 ng/mL Test
105079	Drug-Screen® LSD 10 ng/mL Test
106000	Drug-Screen® PCM 1000 ng/mL Test
106000N-10	Drug-Screen® PCM 1000 ng/mL Test
106002	Drug-Screen® BAR 100 ng/mL Test

106002N-10	Drug-Screen® BAR 100 ng/mL Test
106003	Drug-Screen® BZD 100 ng/mL Test
106003N-10	Drug-Screen® BZD 100 ng/mL Test
106004	Drug-Screen® BUP 5 ng/mL Test
106004N-10	Drug-Screen® BUP 5 ng/mL Test
106004N-10_SSL	Drug-Screen® BUP 5 ng/mL Test
106005	Drug-Screen® COC 50 ng/mL Test
106005_SSL	Drug-Screen® COC 50 ng/mL Test
106005N-10	Drug-Screen® COC 50 ng/mL Test
106005N-10_SSL	Drug-Screen® COC 50 ng/mL Test
106006	Drug-Screen® MTD 50 ng/mL Test
106006N-10	Drug-Screen® MTD 50 ng/mL Test
106008	Drug-Screen® MDMA 50 ng/mL Test
106008_SSL	Drug-Screen® MDMA 50 ng/mL Test
106008N-10	Drug-Screen® MDMA 50 ng/mL Test
106009	Drug-Screen® MOR/OPI 40 ng/mL Test
106009N-10	Drug-Screen® MOR/OPI 40 ng/mL Test
106011	Drug-Screen® PCP 25 ng/mL Test
106013	Drug-Screen® TCA 300 ng/mL Test
106013_SSL	Drug-Screen® TCA 300 ng/mL Test
106013N-10	Drug-Screen® TCA 300 ng/mL Test
106014	Drug-Screen® PPX 300 ng/mL Test
106015	Drug-Screen® MDA 500 ng/mL Test
106016	Drug-Screen® AMP 50 ng/mL Test
106016N-10	Drug-Screen® AMP 50 ng/mL Test
106017	Drug-Screen® THC 12 ng/mL Test
106017_SSL	Drug-Screen® THC 12 ng/mL Test
106017N-10	Drug-Screen® THC 12 ng/mL Test
106018	Drug-Screen® MET 50 ng/mL Test
106018_SSL	Drug-Screen® MET 50 ng/mL Test
106018N-10	Drug-Screen® MET 50 ng/mL Test
106019	Drug-Screen® COT 200 ng/mL Test
106024	Drug-Screen® KET 50 ng/mL Test
106028	Drug-Screen® TML 100 ng/mL Test
106028_SSL	Drug-Screen® TML 100 ng/mL Test
106028N-10	Drug-Screen® TML 100 ng/mL Test
106029	Drug-Screen® FYL 10 ng/mL Test
106030	Drug-Screen® MQL 300 ng/mL Test
106032	Drug-Screen® OXY 50 ng/mL Test

106047	Drug-Screen® TZD 25 ng/mL Test
106047_SSL	Drug-Screen® TZD 25 ng/mL Test
106047N-10	Drug-Screen® TZD 25 ng/mL Test
106097N-10	Drug-Screen® COT 100 ng/mL Test
107002	Drug-Screen® BAR 300 ng/mL Test (4mm)
1110020	Drug-Screen® Multi 2XA Test
1110030	Drug-Screen® Multi 3XA Test
1110030_SSL	Drug-Screen® Multi 3XA Test
1110030N-10	Drug-Screen® Multi 3XA Test
1110031	Drug-Screen® Multi 3XB Test
1110040	Drug-Screen® Multi 4XA Test
1110041	Drug-Screen® Multi 4XB Test
1110050	Drug-Screen® Multi 5XA Test
1110050N-10	Drug-Screen® Multi 5XA Test
1110070	Drug-Screen® Multi 7XA Test
1110080	Drug-Screen® Multi 8XA Test
1110080BA	Drug-Screen® Multi 8XA Barcoded Test
1110080N-10	Drug-Screen® Multi 8XA Test
1110081	Drug-Screen® Multi 8XB Test
1110090	Drug-Screen® Multi 9XA Test
113001	Drug-Screen® AMP 50 ng/ml Saliva (classic) Test
113001P	AMP 50 ng/ml Saliva (classic) Test
113003	Drug-Screen® BZD 10 ng/ml Saliva (classic) Test
113003P	BZD 10 ng/ml Saliva (classic) Test
113004	Drug-Screen® BUP 5 ng/ml Saliva (classic) Test
113004_SSL	Drug-Screen® BUP 5 ng/ml Saliva (classic) Test
113004P	BUP 5 ng/ml Saliva (classic) Test
113005	Drug-Screen® COC 20 ng/ml Saliva (classic) Test
113005P	COC 20 ng/ml Saliva (classic) Test
113006	Drug-Screen® MTD 30 ng/ml Saliva (classic) Test
113006_SSL	Drug-Screen® MTD 30 ng/ml Saliva (classic) Test
113006P	MTD 30 ng/ml Saliva (classic) Test
113007	Drug-Screen® MET 50 ng/ml Saliva (classic) Test
113007_SSL	Drug-Screen® MET 50 ng/ml Saliva (classic) Test

113008	Drug-Screen® MDMA 50 ng/ml Saliva (classic) Test
113009	Drug-Screen® MOR/OPI 40 ng/ml Saliva (classic) Test
113009P	MOR/OPI 40 ng/ml Saliva (classic) Test
113011	Drug-Screen® PCP 10 ng/ml Saliva (classic) Test
113011P	PCP 10 ng/ml Saliva (classic) Test
113012	Drug-Screen® THC 12 ng/ml Saliva (classic) Test
113012_SSL	Drug-Screen® THC 12 ng/ml Saliva (classic) Test
113012P	THC 12 ng/ml Saliva (classic) Test
113013	Drug-Screen® TCA 100 ng/ml Saliva (classic) Test
113013P	TCA 100 ng/ml Saliva (classic) Test
113021	Drug-Screen® EDDP 20 ng/ml Saliva (classic) Test
113021_SSL	Drug-Screen® EDDP 20 ng/ml Saliva (classic) Test
113021P	EDDP 20 ng/ml Saliva (classic) Test
113024	Drug-Screen® KET 100 ng/ml Saliva (classic) Test
113024P	KET 100 ng/ml Saliva (classic) Test
113025	Drug-Screen® COT 50 ng/ml Saliva (classic) Test
113025_SSL	Drug-Screen® COT 50 ng/ml Saliva (classic) Test
113032	Drug-Screen® OXY 20 ng/ml Saliva (classic) Test
113032P	OXY 20 ng/ml Saliva (classic) Test
113033	Drug-Screen® BZD 5 ng/ml Saliva (classic) Test
114010	Drug-Screen® Multi 10CA Saliva (classic) Test
114021	Drug-Screen® Multi 2CC Saliva (classic) Test
114021_SSL	Drug-Screen® Multi 2CC Saliva (classic) Test
114023	Drug-Screen® Multi 2CA Saliva (classic) Test
114024	Drug-Screen® Multi 2CB Saliva (classic) Test
114030	Drug-Screen® Multi 3CC Saliva (classic) Test
114031	Drug-Screen® Multi 3CD Saliva (classic) Test
114040	Drug-Screen® Multi 4CA Saliva (classic) Test

114040N-05	Drug-Screen® Multi 4CA Saliva (classic) Test
114041	Drug-Screen® Multi 4CB Saliva (classic) Test
114051	Drug-Screen® Multi 6CA Saliva (classic) Test
114051N-05	Drug-Screen® Multi 6CA Saliva (classic) Test
114052	Drug-Screen® Multi 6CB Saliva (classic) Test
114053	Drug-Screen® Multi 3CA Saliva (classic) Test
114053_SSL	Drug-Screen® Multi 3CA Saliva (classic) Test
114054	Drug-Screen® Multi 3CB Saliva (classic) Test
114054_SSL	Drug-Screen® Multi 3CB Saliva (classic) Test
114056	Drug-Screen® Multi 5CA Saliva (classic) Test
114056_SSL	Drug-Screen® Multi 5CA Saliva (classic) Test
114057	Drug-Screen® Multi 5CB Saliva (classic) Test
114057_SSL	Drug-Screen® Multi 5CB Saliva (classic) Test
114058	Drug-Screen® Multi 5CC Saliva (classic) Test
114058_SSL	Drug-Screen® Multi 5CC Saliva (classic) Test
114059	Drug-Screen® Multi 5CD Saliva (classic) Test
114059_SSL	Drug-Screen® Multi 5CD Saliva (classic) Test
114060	Drug-Screen® Multi 6CC Saliva (classic) Test
114060_SSL	Drug-Screen® Multi 6CC Saliva (classic) Test
114060N-05	Drug-Screen® Multi 6CC Saliva (classic) Test
114061	Drug-Screen® Multi 6CD Saliva (classic) Test
114061_SSL	Drug-Screen® Multi 6CD Saliva (classic) Test
114062	Drug-Screen® Multi 6CF Saliva (classic) Test
114062_SSL	Drug-Screen® Multi 6CF Saliva (classic) Test
114063	Drug-Screen® Multi 6CG Saliva (classic) Test
114063_SSL	Drug-Screen® Multi 6CG Saliva (classic) Test

	(classic) Test	1160070	Drug-Screen® Multi 7RA Test
114064	Drug-Screen® Multi 6CH Saliva (classic) Test	1160070P	Multi 7RA Test
114065	Drug-Screen® Multi 6CI Saliva (classic) Test	1160080	Drug-Screen® Multi 7RO-AC-A Test
114066	Drug-Screen® Multi 6CJ Saliva (classic) Test	1160080P	Multi 7RO-AC-A Test
114070	Drug-Screen® Multi 7CA Saliva (classic) Test	1160090	Drug-Screen® Multi 9RA Test
114070_SSL	Drug-Screen® Multi 7CA Saliva (classic) Test	1160090_SSL	Drug-Screen® Multi 9RA Test
114071	Drug-Screen® Multi 7CB Saliva (classic) Test	1160090P	Multi 9RA Test
114072	Drug-Screen® Multi 7CC Saliva (classic) Test	1160090P_SSL	Multi 9RA Test
114080	Drug-Screen® Multi 8CA Saliva (classic) Test	1160091	Drug-Screen® Multi 9RB Test
114081	Drug-Screen® Multi 8CB Saliva (classic) Test	1160091_SSL	Drug-Screen® Multi 9RB Test
114091	Drug-Screen® Multi 9CB Saliva (classic) Test	1160091P	Multi 9RB Test
114092	Drug-Screen® Multi 9CD Saliva (classic) Test	1160091P_SSL	Multi 9RB Test
114150	Drug-Screen® Multi 5CE Saliva (classic) Test	116050	Drug-Screen® Multi 5A Saliva (advanced) Test
114050_SSL	Drug-Screen® Multi 5CE Saliva (classic) Test	116050_SSL	Drug-Screen® Multi 5A Saliva (advanced) Test
114151	Drug-Screen® Multi 5CF Saliva (classic) Test	116050N-05	Drug-Screen® Multi 5A Saliva (advanced) Test
114151_SSL	Drug-Screen® Multi 5CF Saliva (classic) Test	116050P	Multi 5A Saliva (advanced) Test
115020	Drug-Screen® Multi 2GA Saliva (integrated) Test	1770020	Drug-Screen® Cup III Round 2RA Test
115030	Drug-Screen® Multi 3GA Saliva (integrated) Test	1770030	Drug-Screen® Cup III Round 3RA Test
115050	Drug-Screen® Multi 5GA Saliva (integrated) Test	1770031	Drug-Screen® Cup III Round 3RB Test
115051	Drug-Screen® Multi 6GA Saliva (integrated) Test	1770031_SSL	Drug-Screen® Cup III Round 3RB Test
115052	Drug-Screen® Multi 6GB Saliva (integrated) Test	1770040	Drug-Screen® Cup III Round 4RA Test
115053	Drug-Screen® Multi 6GC Saliva (integrated) Test	1770050	Drug-Screen® Cup III Round 5RA Test
115053_SSL	Drug-Screen® Multi 6GC Saliva (integrated) Test	1770051	Drug-Screen® Cup III Round 5RB Test
115054	Drug-Screen® Multi 6GD Saliva (integrated) Test	1770060	Drug-Screen® Cup III Round 6RA Test
115054_SSL	Drug-Screen® Multi 6GD Saliva (integrated) Test	1770060_SSL	Drug-Screen® Cup III Round 6RA Test
115054N-05	Drug-Screen® Multi 6GD Saliva (integrated) Test	1770061	Drug-Screen® Cup III Round 6RB Test
		1770061_SSL	Drug-Screen® Cup III Round 6RB Test
		1770062	Drug-Screen® Cup III Round 6RC Test
		1770070	Drug-Screen® Cup III Round 7RA Test
		1770080	Drug-Screen® Cup III Round 8RA Test
		1770090	Drug-Screen® Cup III Round 9RA Test
		1770100	Drug-Screen® Cup III Round 10RA Test
		1770110	Drug-Screen® Cup III Round 11RA Test
		1770120	Drug-Screen® Cup III Round 12RA Test
		1780060	Drug-Screen® Cup V 6A Test
		1023020P	Multi 2 (3mm) Test
		2023030P	Multi 3 (3mm) Test
		2023038P	Multi 3H (3mm) Test
		2023038P_SSL	Multi 3H (3mm) Test

2023045P	Multi 4F (3mm) Test	620044	Drug-Screen® COC 200 ng/ml Test
2023050P	Multi 5 (3mm) Test	620045	Drug-Screen® COC 300 ng/ml Test
2023060P	Multi 6A (3mm) Test	620045_SSL	Drug-Screen® COC 300 ng/ml Test
2023060P_SSL	Multi 6A (3mm) Test	620054	Drug-Screen® THC 25 ng/ml Test
2023070P	Multi 7A (3mm) Test	620055	Drug-Screen® THC 50 ng/ml Test
2023071P	Multi 7B (3mm) Test	620055_SSL	Drug-Screen® THC 50 ng/ml Test
2023071P_SSL	Multi 7B (3mm) Test	620057	Drug-Screen® THC 150 ng/ml Test
2023080P	Multi 8A (3mm) Test	620063	Drug-Screen® BZD 200 ng/ml Test
2023087P	Multi 8AJ (3mm) Test	620063_SSL	Drug-Screen® BZD 200 ng/ml Test
2023090P	Multi 9 (3mm) Test	620065	Drug-Screen® BZD 300 ng/ml Test
2023101P	Multi 10E (3mm) Test	620065_SSL	Drug-Screen® BZD 300 ng/ml Test
2023102P	Multi 10 (3mm) Test	620075	Drug-Screen® MTD 300 ng/ml Test
2023102P_SSL	Multi 10 (3mm) Test	620075_SSL	Drug-Screen® MTD 300 ng/ml Test
2023165P	Multi 6P (3mm) Test	620085	Drug-Screen® BAR 300 ng/ml Test
2104050	Drug-Screen® Multi 5HC Saliva Test Hawk-I	620095	Drug-Screen® TCA 1000 ng/ml Test
311784	Drug-Screen® Multi 2 Test	620103	Drug-Screen® MDA 500 ng/ml Test
311785	Drug-Screen® Multi 2 Test	620105	Drug-Screen® MDMA/XTC 500 ng/ml Test
311898	Drug-Screen® Multi 10 Test	620108	Drug-Screen® PCP 25 ng/ml Test
360006	Alcohol Screen Saliva Test	620108_SSL	Drug-Screen® PCP 25 ng/ml Test
360006_SSL	Alcohol Screen Saliva Test	620150	Drug-Screen® BUP 10 ng/ml Test
360006N-10	Alcohol Screen Saliva Test	620150_SSL	Drug-Screen® BUP 10 ng/ml Test
360006N-10_SSL	Alcohol Screen Saliva Test	620160	Drug-Screen® EDDP 100 ng/ml Test
360084	Alcohol-Screen Breath Test	620170	Drug-Screen® TML 100 ng/ml Test
360085	Alcohol-Screen Breath Test	620190	Drug-Screen® FYL 10 ng/ml Test
620006	Drug-Screen® AMP 300 ng/ml Test	620193	Drug-Screen® COT 200 ng/ml Test
620007	Drug-Screen® MET 300 ng/ml Test	620193_SSL	Drug-Screen® COT 200 ng/ml Test
620013	Drug-Screen® AMP 500 ng/ml Test	620195	Drug-Screen® KET 100 ng/ml Test
620015	Drug-Screen® AMP 1000 ng/ml Test	620197	Drug-Screen® PPX 300 ng/ml Test
620023	Drug-Screen® MET 500 ng/ml Test	620302	Drug-Screen® Multi 5M Test
620025	Drug-Screen® MET 1000 ng/ml Test	620302N-10	Drug-Screen® Multi 5M Test
620033	Drug-Screen® MOR/OPI 100 ng/ml Test	620402	Drug-Screen® Multi 5 Test
620035	Drug-Screen® MOR/OPI 300 ng/ml Test	620402_SSL	Drug-Screen® Multi 5 Test
620035_SSL	Drug-Screen® MOR/OPI 300 ng/ml Test	620402N-10	Drug-Screen® Multi 5 Test
620035P	MOR/OPI 300 ng/ml Test	620402P	Multi 5 Test
620037	Drug-Screen® MOR/OPI 2000 ng/ml Test	620402P_SSL	Multi 5 Test
620037_SSL	Drug-Screen® MOR/OPI 2000 ng/ml Test	620602	Drug-Screen® Multi 6 Test
620043	Drug-Screen® COC 100 ng/ml Test	620602_SSL	Drug-Screen® Multi 6 Test
		620602N-10	Drug-Screen® Multi 6 Test
		620602N-10_SSL	Drug-Screen® Multi 6 Test
		620602P	Multi 6 Test

620602P_SSL	Multi 6 Test
620802	Drug-Screen® Multi 10E Test
620802_SSL	Drug-Screen® Multi 10E Test
620802N-10	Drug-Screen® Multi 10E Test
620802P	Multi 10E Test
620902	Drug-Screen® Multi 3 Test
620902N-10	Drug-Screen® Multi 3 Test
621002	Drug-Screen® Multi 3C Test
621102	Drug-Screen® Multi 7EB Test
621102_SSL	Drug-Screen® Multi 7EB Test
621102N-10	Drug-Screen® Multi 7EB Test
621102P	Multi 7EB Test
621202	Drug-Screen® Multi 5B Test
621402	Drug-Screen® Multi 5MB Test
621702	Drug-Screen® Multi 5E Test
621702_SSL	Drug-Screen® Multi 5E Test
621702N-10	Drug-Screen® Multi 5E Test
621802	Drug-Screen® Multi 10L Test
621802_SSL	Drug-Screen® Multi 10L Test
621802N-10	Drug-Screen® Multi 10L Test
622002	Drug-Screen® Multi 7L Test
622002_SSL	Drug-Screen® Multi 7L Test
622102	Drug-Screen® Multi 4E Test
622102N-10	Drug-Screen® Multi 4E Test
622202	Drug-Screen® Multi 5EB Test
622202_SSL	Drug-Screen® Multi 5EB Test
622202N-10	Drug-Screen® Multi 5EB Test
622302	Drug-Screen® Multi 5SE Test
622402	Drug-Screen® Multi 6E Test
622402_SSL	Drug-Screen® Multi 6E Test
622402N-10	Drug-Screen® Multi 6E Test
622402N-10_SSL	Drug-Screen® Multi 6E Test
622502	Drug-Screen® Multi 4B Test
622602	Drug-Screen® Multi 4EB Test
622702	Drug-Screen® Multi 5SB Test
622802	Drug-Screen® Multi 7V Test
622802_SSL	Drug-Screen® Multi 7V Test
623002	Drug-Screen® Multi 3T Test
630001	Drug-Screen® Creatinine Test
630001N-10	Drug-Screen® Creatinine Test

630002	Drug-Screen® Multi 4V Test
630002_SSL	Drug-Screen® Multi 4V Test
630002N-10	Drug-Screen® Multi 4V Test
630302	Drug-Screen® Multi 4T Test
630302_SSL	Drug-Screen® Multi 4T Test
630402	Drug-Screen® Multi 4M Test
630402_SSL	Drug-Screen® Multi 4M Test
630402N-10	Drug-Screen® Multi 4M Test
630402N-10_SSL	Drug-Screen® Multi 4M Test
630602	Drug-Screen® Multi 5S Test
630602_SSL	Drug-Screen® Multi 5S Test
630602N-10	Drug-Screen® Multi 5S Test
630602N-10_SSL	Drug-Screen® Multi 5S Test
630802	Drug-Screen® Multi 7 Test
630802_SSL	Drug-Screen® Multi 7 Test
630802N-10	Drug-Screen® Multi 7 Test
630802N-10_SSL	Drug-Screen® Multi 7 Test
630925	UrineCheck 7 DOA Adulteration Test
930925_SSL	UrineCheck 7 DOA Adulteration Test
640002	Drug-Screen® Multi 5T Test
640002_SSL	Drug-Screen® Multi 5T Test
640202	Drug-Screen® Multi 4H Test
640302	Drug-Screen® Multi 6T Test
640302_SSL	Drug-Screen® Multi 6T Test
640302N-10	Drug-Screen® Multi 6T Test
640302N-10_SSL	Drug-Screen® Multi 6T Test
640302P	Multi 6T Test
640302P_SSL	Multi 6T Test
640402	Drug-Screen® Multi 6B Test
640402N-10	Drug-Screen® Multi 6B Test
640702	Drug-Screen® Multi 11T Test
640702_SSL	Drug-Screen® Multi 11T Test
640702N-10	Drug-Screen® Multi 11T Test
640702P	Multi 11T Test
640702P_SSL	Multi 11T Test
640802	Drug-Screen® Multi 6TB Test
640802_SSL	Drug-Screen® Multi 6TB Test
830020	Drug-Screen® Cup Side Panel 2CA Test

830033	Drug-Screen® Cup Side Panel 3CA Test
830042	Drug-Screen® Cup Side Panel 4CA Test
830043	Drug-Screen® Cup Side Panel 4A-AC-C Test
830050	Drug-Screen® Cup Side Panel 5CA Test
830050_SSL	Drug-Screen® Cup Side Panel 5CA Test
830052	Drug-Screen® Cup Side Panel 5CC Test
830053	Drug-Screen® Cup Side Panel 5CD-AC-C Test
830060	Drug-Screen® Cup Side Panel 6CA Test
830060P	Drug-Screen® Cup Side Panel 6CA Test
830060P_SSL	Drug-Screen® Cup Side Panel 6CA Test
830061	Drug-Screen® Cup Side Panel 6CB Test
830061_SSL	Drug-Screen® Cup Side Panel 6CB Test
830062	Drug-Screen® Cup Side Panel 6CD Test
830062_SSL	Drug-Screen® Cup Side Panel 6CD Test
830063	Drug-Screen® Cup Side Panel 6CF Test
830064	Drug-Screen® Cup Side Panel 6CG Test
830065	Drug-Screen® Cup Side Panel 6CH Test
830071	Drug-Screen® Side Panel Cup 7CB Test
830080	Drug-Screen® Cup Side Panel 8CA Test
830080_SSL	Drug-Screen® Cup Side Panel 8CA Test
830081	Drug-Screen® Cup Side Panel 8CB Test
830081_SSL	Drug-Screen® Cup Side Panel 8CB Test
830082	Drug-Screen® Cup Side Panel 8CC Test
830082_SSL	Drug-Screen® Cup Side Panel 8CC Test
830090	Drug-Screen® Cup Side Panel 9CA Test
830101	Drug-Screen® Cup Side Panel 10CB Test
830101_SSL	Drug-Screen® Cup Side Panel 10CB Test
910030	Drug-Screen® Cup II 3A-AC-C Test
910040	Drug-Screen® Cup II 4A Test
910040_SSL	Drug-Screen® Cup II 4A Test

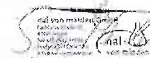
910042	Drug-Screen® Cup II 4C Test
910042_SSL	Drug-Screen® Cup II 4C Test
910043	Drug-Screen® Cup II 4D Test
910050	Drug-Screen® Cup II 5A Test
910050_SSL	Drug-Screen® Cup II 5A Test
910051	Drug-Screen® Cup II 5B Test
910051_SSL	Drug-Screen® Cup II 5B Test
910051P	Cup II 5B Test
910053	Drug-Screen® Cup II 5C Test
910054	Drug-Screen® Cup II 5D Test
910054_SSL	Drug-Screen® Cup II 5D Test
910055	Drug-Screen® Cup II 5E Test
910055_SSL	Drug-Screen® Cup II 5E Test
910056	Drug-Screen® Cup II 5F Test
910056_SSL	Drug-Screen® Cup II 5F Test
910060	Drug-Screen® Cup II 6A Test
910060_SSL	Drug-Screen® Cup II 6A Test
910061	Drug-Screen® Cup II 6B Test
910061_SSL	Drug-Screen® Cup II 6B Test
910062	Drug-Screen® Cup II 6C Test
910062_SSL	Drug-Screen® Cup II 6C Test
910063	Drug-Screen® Cup II 6D + 6ADU Test
910067	Drug-Screen® Cup II 6G Test
910067_SSL	Drug-Screen® Cup II 6G Test
910068	Drug-Screen® Cup II 6H Test
910068_SSL	Drug-Screen® Cup II 6H Test
910069	Drug-Screen® Cup II 6I Test
910069_SSL	Drug-Screen® Cup II 6I Test
910070	Drug-Screen® Cup II 7A Test
910070_SSL	Drug-Screen® Cup II 7A Test
910071	Drug-Screen® Cup II 7B Test
910071_SSL	Drug-Screen® Cup II 7B Test
910072	Drug-Screen® Cup II 7J-AC-A Test
910073	Drug-Screen® Cup II 7D Test
910074	Drug-Screen® Cup II 7E Test
910075	Drug-Screen® Cup II 7F Test
910076	Drug-Screen® Cup II 7G Test
910076_SSL	Drug-Screen® Cup II 7G Test
910077	Drug-Screen® Cup II 7H Test
910078	Drug-Screen® Cup II 7I-AC-A Test
910078_SSL	Drug-Screen® Cup II 7I-AC-A Test

910079	Drug-Screen® Cup II 7J Test
910079_SSL	Drug-Screen® Cup II 7J Test
910080	Drug-Screen® Cup II 8A Test
910080_SSL	Drug-Screen® Cup II 8A Test
910081	Drug-Screen® Cup II 8B Test
910081_SSL	Drug-Screen® Cup II 8B Test
910082	Drug-Screen® Cup II 8C Test
910082_SSL	Drug-Screen® Cup II 8C Test
910082P	Cup II 8C Test
910083	Drug-Screen® Cup II 8D Test
910083_SSL	Drug-Screen® Cup II 8D Test
910084	Drug-Screen® Cup II 8E Test
910084_SSL	Drug-Screen® Cup II 8E Test
910085	Drug-Screen® Cup II 8F Test
910086	Drug-Screen® Cup II 8G Test
910087	Drug-Screen® Cup II 8H Test
910087_SSL	Drug-Screen® Cup II 8H Test
910088	Drug-Screen® Cup II 9F Test
910088_SSL	Drug-Screen® Cup II 9F Test
910089	Drug-Screen® Cup II 8AA Test
910089_SSL	Drug-Screen® Cup II 8AA Test
910091	Drug-Screen® Cup II 9B Test
910091P	Cup II 9B Test
910092	Drug-Screen® Cup II 9C Test
910092_SSL	Drug-Screen® Cup II 9C Test
910093	Drug-Screen® Cup II 9D Test
910093_SSL	Drug-Screen® Cup II 9D Test
910094	Drug-Screen® Cup II 9E Test
910094_SSL	Drug-Screen® Cup II 9E Test
910095	Drug-Screen® Cup II 9F-AC-A Test
910096	Drug-Screen® Cup II 9G-AC-A Test
910097	Drug-Screen® Cup II 9H Test
910098	Drug-Screen® Cup II 9A-AC-C
910101	Drug-Screen® Cup II 10B Test
910101_SSL	Drug-Screen® Cup II 10B Test
910102	Drug-Screen® Cup II 10C Test
910102_SSL	Drug-Screen® Cup II 10C Test
910103	Drug-Screen® Cup II 10A Test
910104	Drug-Screen® Cup II 10D Test
910104_SSL	Drug-Screen® Cup II 10D Test

910105	Drug-Screen® Cup II 10E-AC-B Test
910105_SSL	Drug-Screen® Cup II 10E-AC-B Test
910106	Drug-Screen® Cup II 10F-AC-B Test
910110	Drug-Screen® Cup II 11 Test
910110_SSL	Drug-Screen® Cup II 11 Test
910111	Drug-Screen® Cup II 11B Test
910111_SSL	Drug-Screen® Cup II 11B Test
910112	Drug-Screen® Cup II 11C Test
910112_SSL	Drug-Screen® Cup II 11C Test
910113	Drug-Screen® Cup II 11D Test
910120	Drug-Screen® Cup II 12A Test
910120_SSL	Drug-Screen® Cup II 12A Test
910122	Drug-Screen® Cup II 12C Test
910124	Drug-Screen® Cup II 12D Test
910124_SSL	Drug-Screen® Cup II 12D Test
910125	Drug-Screen® Cup II 12E Test
910126ADP-BA	Drug-Screen® Cup II 12F-AC-F Barcoded Test
910140	Drug-Screen® Cup II 4A Test
911060	Drug-Screen® Cup II 6J Test
911060_SSL	Drug-Screen® Cup II 6J Test
911060P	Cup II 6J Test
911060P_SSL	Cup II 6J Test
911061	Drug-Screen® Cup II 6K Test
911062	Drug-Screen® Cup II 6L Test
911070	Drug-Screen® Cup II 7K Test
911080	Drug-Screen® Cup II 8I-AC-B Test
911081	Drug-Screen® Cup II 8A-AC-A Test
911081_SSL	Drug-Screen® Cup II 8A-AC-A Test
911082	Drug-Screen® Cup II 8J-AC-BE Test
911082_SSL	Drug-Screen® Cup II 8J-AC-BE Test

This document is valid until 30.11.2019.

Moers, 01.12.2017


Sandra von Minden
CEO

**EC Declaration of conformity for medical devices
according to annex II of directive 93/42/EC for medical devices**

The procedure for EC declaration established a quality assurance system according to
EN ISO 9001:2008 and EN ISO 13485:2003+AC:2009.



We

Name of producer: MACHEREY-NAGEL GmbH & Co. KG

Address: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
D- 52355 Dueren
Germany

confirm that the following test sticks

Reference number: 91312

Name of product: Quantofix Peroxide 100 test strips

Type: Class I

Test strips for the control of residues in dialyzers

Registration number: DE/CA21/MACHEREY/2004/06/A/0001

are manufactured in compliance with the European Directive 93/42/EC.

Dueren, July 01, 2014

i.A. Dr. Hoffmann (QC)

www.mn-net.com



MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Düren · Germany
Germany
and international:
Tel.: +49 24 21 989-0
Fax: +49 24 21 968-199
E-mail: info@mn-net.com
Switzerland:
MACHEREY-NAGEL AG
Tel.: +41 82 388 55 00
Fax: +41 82 388 55 05
E-mail: sales-ch@mn-net.com
France:
MACHEREY-NAGEL EURL
Tel.: +33 388 68 22 68
Fax: +33 388 51 76 88
E-mail: sales-fr@mn-net.com

USA:
MACHEREY-NAGEL Inc.
Tel.: +1 484 821 0984
Fax: +1 484 821 1272
E-mail: sales-us@mn-net.com

EC Declaration of conformity for In-vitro-diagnostics

according to annex III of directive 98/79/EC for In-vitro-diagnostics

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2003+AC:2009.



We

Name of Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Address: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Strasse 6-8
D - 52355 Dueren
Germany

confirm that the following test sticks

Reference number: 921 20
Name of Product: pH-Fix 4,5-10,0 test strips
Type: Test strips for the pH determination in urine,
for self-testing
EDMS 11-70-02-01-00
URINE SINGLE TEST STRIPS
Registration number: DE/CA21/MACHEREY/2002/11/IVD/0003/Ä

are manufactured in compliance with the European Directive 98/79/EC.

Dueren, April 1th 2014

I.A. Dr. J. Hoffmann (Head of QC)

www.mn-net.com

MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Dueren · Germany
Germany
and International:
Tel.: +49 24 21 969-0
Fax: +49 24 21 969-199
E-mail: info@mn-net.com

Switzerland:
MACHEREY-NAGEL AG
Tel.: +41 62 388 55 00
Fax: +41 62 388 55 05
E-mail: sales-ch@mn-net.com

France:
MACHEREY-NAGEL EURL
Tel.: +33 388 58 22 68
Fax: +33 388 51 76 88
E-mail: sales-fr@mn-net.com

USA:
MACHEREY-NAGEL Inc.
Tel.: +1 484 621 0984
Fax: +1 484 621 1272
E-mail: sales-us@mn-net.com

EC Declaration of conformity for In-vitro-diagnostics
(according to annex III of directive 98/79/EC for In-vitro-diagnostics)

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2003+A1:2007.



We

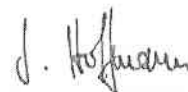
Name of producer: MACHEREY-NAGEL GmbH & Co. KG
Address: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Strasse 6-8
52355 Dueren
Germany

confirm that the following test strips

Reference number: 921 35
Name of product: pH-Fix 3.1-8.3 test strips
Type: Test strips for the determination of the pH-value in saliva
EDMS 11-70-90-90-00
Registration number: DE/CA21/ /MACHEREY/2002/11/IVD/0009

are manufactured in compliance with the European Directive 98/79/EC.

Dueren, April 01 2011



i.A. Dr. Hoffmann (QC)

EC Declaration of conformity for medical devices
according to annex II of directive 93/42/EC for medical devices

The procedure for EC declaration established a quality assurance system according to
EN ISO 9001:2008 and EN ISO 13485:2003+A1:2007.



We

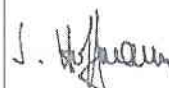
Name of producer: MACHEREY-NAGEL GmbH & Co. KG**Address:** MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
D- 52355 Dueren
Germany

confirm that the following test sticks

Reference number: 91343**Name of product:** QUANTOFIX® Glutaraldehyde test strips**Type:** Class I**Registration number:** Test strips for checking the concentration of
glutaraldehyde in disinfecting solutions
DE/CA21/MACHEREY/2004/06/A/0001

are manufactured in compliance with the European Directive 93/42/EC.

Dueren, August 12, 2013



i.A. Dr. Hoffmann (QC)

EC Declaration of conformity for medical devices
according to annex II of directive 93/42/EC for medical devices

The procedure for EC declaration established a quality assurance system according to
EN ISO 9001:2008 and EN ISO 13485:2003+A1:2007.



We

Name of producer: MACHEREY-NAGEL GmbH & Co. KG

Address: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
D- 52355 Dueren
Germany

confirm that the following test sticks

Reference number: 91341
Name of product: QUANTOFIX® Peracetic Acid 500 test strips
Type: Class I
Test strips for checking the concentration of
peracetic acid in dialysis equipment
Registration number: DE/CA21/MACHEREY/2004/06/A/0001

are manufactured in compliance with the European Directive 93/42/EC.

Dueren, August 12, 2013



i.A. Dr. Hoffmann (QC)

**EC Declaration of conformity for medical devices
according to annex II directive 93/42/EC for medical devices**

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.



We

Name of producer:

MACHEREY-NAGEL GmbH & Co. KG

Address:MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
D- 52355 Dueren
Germany

confirm that the following test sticks

Name of product**Reference numbers**

DiaQuant® Peracetic Acid	932 001
DiaQuant® Peroxide	932 002
DiaQuant® pH	932 003
DiaQuant® Chlorine	932 004
DiaQuant® Water Hardness	932 005
DiaQuant® Peracetic Acid P	932 006
DiaQuant® Peroxide S	932 007

Type:**Class I**

Test strips for the control of concentrations and residues of hydrogen peroxide, peracetic acid and/or other acids in dialysis equipment.

Test strips for the control of low water hardness when preparing dialysis liquid.

Registration number:DE/CA21/MACHEREY/2004/06/A/0001
DE/CA21/MACHEREY/2004/11/A/0002

are manufactured in compliance with the European Directive 93/42/EC.

Dueren, June 01, 2015



i.A. Dr. Hoffmann (QC)

EC Declaration of Conformity

according to Annex III of the IVD Directive 98/79/EC

The procedure for EC declaration of conformity was established according to the IVD directive 98/79/EC on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.



We

Name of manufacturer

MACHEREY-NAGEL GmbH & Co. KG

Address:

 MACHEREY-NAGEL GmbH & Co. KG
 Neumann-Neander-Strasse 6-8
 D - 52355 Düren
 Germany

confirm that the following pH test strips

Name of product

pH-Fix 4.0-7.0 test strips

Reference number

92137

Type:

 Indicator test strips for the measurement of the
 vaginal pH value
 EDMS code 11-70-90-90-00
 Other Clin. Chem. Rapid Tests

Classification:

Other IVDs, professional use

Registration number:

DE/CA21/MACHEREY/2002/11/IVD/0006

are manufactured in compliance with the European IVD Directive 98/79/EC.

Düren, April 10, 2017



 ppa. Markus Meusel
 QAM, Manager Regulatory Affairs

www.mn-net.com


MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Düren · Germany

DE/International:

Tel.: +49 24 21 969-0

Fax: +49 24 21 969-199

 E-mail: info@mn-net.com

CH:

Tel.: +41 62 388 55 00

Fax: +41 62 388 55 05

 E-mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 68 22 68

Fax: +33 388 51 76 88

 E-mail: sales-fr@mn-net.com

US:

Tel.: +1 484 821 0984

Fax: +1 484 821 1272

 E-mail: sales-us@mn-net.com

1/1

EC Declaration of Conformity

The procedure for EC declaration was established according to the IVD directive 98/79/EC on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.



We

Name of manufacturer

MACHEREY-NAGEL GmbH & Co. KG

Address:

MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Strasse 6-8
D - 52355 Dueren
Germany

confirm that the following product for professional use

Name of product

Medi-Test Control

Reference number, REF

930 38

Type:

Other calibrators and standards (CC)
EDMS 11-50-03-90-00

Registration number:

DE/CA21/MACHEREY/2002/11/IVD/0007

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 12.02.2014

J.A. Markus Meusel (QA Manager)

EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.



We

Name of manufacturer

MACHEREY-NAGEL GmbH & Co. KG

Address:

MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Strasse 6-8
D - 52355 Dueren
Germany

confirm that the following test strips for professional use

Name of product	Reference numbers
Medi-Test Glucose PN	93017; 930965
Medi-Test Glucose	93001; 93024
Medi-Test Glucose 3	93003; 93026
Medi-Test Glucose/Keton	93020; 93025
Medi-Test Protein 2	93004; 93027
Medi-Test Keton	93005; 93028
Medi-Test Nitrit	93006; 93029
Medi-Test Combi 2	93015; 93037
Medi-Test Urbi	93012
Medi-Test Combi 3	93050
Medi-Test Combi 3A	93007; 93030
Medi-Test Combi 5	93009; 93032
Medi-Test Combi 5N	93035; 93036
Medi-Test Combi 5S	93055
Medi-Test Combi 6	93018; 93078
Medi-Test Combi 6A	93013; 93034
Medi-Test Combi 7	93010; 93022
Medi-Test Combi 7L	93031
Medi-Test Combi 8L	93021
Medi-Test Combi 9	93011; 93023
Medi-Test Combi 10	93056
Medi-Test Combi 10L	93058; 93079
Medi-Test Combi 10 SGL	93067; 93077
Medi-Test URYXXON Stick 10	93068; 930872
Medi-Test Combi 11	93060; 930871
Medi-Test Mikroalbumin	930874

www.mn-net.com



MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Dueren · Germany

DE / International:

Tel.: +49 24 21 969-0

Fax: +49 24 21 969-199

E-mail: info@mn-net.com

CH:

Tel.: +41 62 388 55 00

Fax: +41 62 388 55 05

E-mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 68 22 68

Fax: +33 388 51 76 88

E-mail: sales-fr@mn-net.com

US:

Tel.: +1 484 621 0984

Fax: +1 484 821 1272

E-mail: sales-us@mn-net.com

EC Declaration of conformity for medical devices

(according to annexes I and VII of directive 93/42/EC for medical devices)

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.



We

Name of producer: MACHEREY-NAGEL GmbH & Co. KG**Address:** MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
D- 52355 Dueren
Germany

confirm that the following test sticks

Reference number: 91210
Name of product: Aquadur® Sensitive 100 test strips
Type: Class I
Test strips for the control of low water hardness
when preparing dialysis liquid
Registration number: DE/CA21/MACHEREY/2004/11/A/0002

are manufactured in compliance with the European Directive 93/42/EC.

Dueren, April 01, 2016

i.A. Dr. Hoffmann (QC)

EC DECLARATION OF CONFORMITY

according to Annex III of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang III der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® Relax
REF 930 88

URYXXON® Relax
REF 930 88

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysegerät

is classified as **all other IVD** according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als **sonstiges IVD** klassifiziert ist

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

In addition, it meets the requirements according to the following directive

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

European directive 2011/65/EU on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment (RoHS 2)

Europäische Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS 2)

applied harmonized standards

angewandte Harmonisierte Normen

DIN EN ISO 9001:2008
DIN EN ISO 13485:2012 + AC:2012
DIN EN ISO 14971:2012

DIN EN ISO 18113-1:2010
DIN EN ISO 18113-3:2010
DIN EN 13612:2002
DIN EN 980:2008

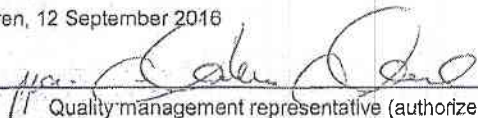
DIN EN ISO 15223-1:2013
DIN EN 62366:2008
DIN EN 62304:2006

DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016



Quality management representative (authorized representative)

www.mn-net.com



MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Düren · Germany

DE / International:

Tel.: +49 24 21 969-0
Fax: +49 24 21 969-199
E-mail: info@mn-net.com

CH:

Tel.: +41 62 388 65 00
Fax: +41 62 388 65 05
E-mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 68 22 68
Fax: +33 388 51 76 68
E-mail: sales-fr@mn-net.com

US:

Tel.: +1 484 821 0984
Fax: +1 484 821 1272
E-mail: sales-us@mn-net.com



Istituto Superiore di Sanità

Certificato n° **QPZ-1725-14**
Certificate no.

Addendum n° **//-//**
addendum no.

Organismo Notificato 0373
Sezione Presso O.N.DI.CO.
Notified Body 0373
Unit relating to O.N.DI.CO.

Data di emissione **01.07.2014**
Issue date
Data di scadenza **30.06.2019**
Expiry date

APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITÀ DELLA PRODUZIONE E/O DELLA STERILIZZAZIONE

secondo l'Allegato V della Direttiva Europea 93/42/CEE e
successive modifiche ed integrazioni.
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e
successive modifiche ed integrazioni)

L'Istituto Superiore di Sanità, Organismo
Notificato 0373, certifica che il sistema di
garanzia della qualità della produzione e/o
della sterilizzazione attuato da

APPROVAL OF QUALITY ASSURANCE SYSTEM FOR PRODUCTION AND/OR STERILIZATION

according to Annex V of EC Directive 93/42/EEC
and subsequent modifications and integrations.
(transposed in Italy by the D.Lgs. n. 46 issued on
24.02.1997 and subsequent modifications and integrations)

The Istituto Superiore di Sanità, Notified Body
0373, certifies that the quality assurance system
for the production
and/or sterilization enforced by

MEUS S.r.l.

Sede Legale/ Registered Office:
Via Leonardo Da Vinci, 24/B - 35028 Piove di Sacco (PD) ITALIA

Altre sedi del Fabbrikante /Other sites of the Manufacturer:
Sede Produttiva/ Production Site: Via dell'Industria, 16 - 35020 Arzergrande (PD) Italia

per il dispositivo/i

for the device(s)

**MD 0102-Dispositivi non attivi per iniezione, infusione, trasfusione e dialisi,
sterili/Non-active devices for injection, infusion, transfusion and dialysis, sterile;**
**MD 0115-Dispositivo monouso non attivo, sterile/Non - active disposable device,
sterile (vedi allegato tecnico/ see technical sheet)***

è conforme ai requisiti applicabili della
Direttiva Europea 93/42/CEE e successive
modifiche ed integrazioni.

is in compliance with the applicable
requirements of Council Directive 93/42/EEC
and subsequent modifications and integrations.

Il Direttore dell'O.N.DI.CO.
The Director of O.N.DI.CO.
(Dr. Carmine Guarino)



* L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integral part of this Certificate.



Istituto Superiore di Sanità

ALLEGATO TECNICO

Il Certificato n°
The Certificate no.

QPZ-1725-14

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

Organismo Notificato 0373
Sezione Presso O.N.D.I.CO.

Notified Body 0373

Unit relating to O.N.D.I.CO.

TECHNICAL SHEET

Addendum n°
addendum no.

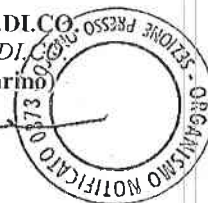
//-//

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

MD 0102-Dispositivi non attivi per iniezione, infusione, trasfusione e dialisi, sterili/Non-active devices for injection, infusion, transfusion and dialysis, sterile
Classe (Class): IIa

Nome prodotto (Product name)	Codice (Code)
Aghi, sterili	1526502, 15201, 1526504, 15213, 1526506, 15225, 15176, 15181, 15164, 15193
Aghi con dispositivo di sicurezza per prelievo sangue con cannula, sterili	15520, 15565, 15521, 15566, 15522, 15567
Aghi Crystal con Holder per prelievo di sangue con provette con vuoto predeterminato	156720, 156721, 156722
Aghi Crystal con Holder e dispositivo di sicurezza per prelievo di sangue con provette con vuoto predeterminato	157520, 157521, 157522

Il Direttore dell'O.N.D.I.CO.
The Director of O.N.D.I.CO.
(Dr. Carmine Guarino)





Istituto Superiore di Sanità

Organismo Notificato 0373

Sezione Presso O.N.DI.CO.

Notified Body 0373

Unit relating to O.N.DI.CO.

ALLEGATO TECNICO

Il Certificato n°
The Certificate no.

QPZ-1725-14

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

TECHNICAL SHEET

Addendum n°
addendum no.

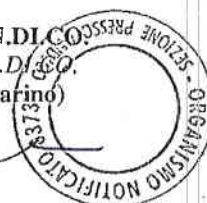
//-//

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

MD 0115-Dispositivo monouso non attivo, sterile/Non – active disposable device, sterile	
Classe (Class): IIa	
<i>Nome prodotto</i> (Product name)	<i>Codice</i> (Code)
<i>Adattatori Luer, sterili</i>	<i>1526537, 1526537A</i>

Il presente certificato sostituisce il certificato QPZ 1691 14 del 09/03/2014.
This certificate supersedes the previous certificate QPZ 1691 14 issued on 09/03/2014.

Il Direttore dell'O.N.DI.CO.
The Director of O.N.DI.CO.
(Dr. Carmine Guarino)





Istituto Superiore di Sanità

Organismo Notificato 0373
Sezione Presso O.N.DI.CO.
Notified Body 0373
Unit relating to O.N.DI.CO.

Certificato n° **QPS-0465-14**
 Certificate no.

Addendum n° **//-//**
 addendum no.

Data di emissione **01.07.2014**
Issue date
 Data di scadenza **30.06.2019**
Expiry date

APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITÀ DELLA PRODUZIONE E/O DELLA STERILIZZAZIONE

secondo l'Allegato V della Direttiva Europea 93/42/CEE e
 successive modifiche ed integrazioni
*(received in Italy with the D.Lgs. n. 46 del 24.02.1997 e
 successive modifiche ed integrazioni)*

APPROVAL OF QUALITY ASSURANCE SYSTEM FOR PRODUCTION AND/OR STERILIZATION

according to Annex V of EC Directive 93/42/EEC
 and subsequent modifications and integrations
*(transposed in Italy by the D.Lgs. n. 46 issued on
 24.02.1997 and subsequent modifications and integrations)*

L'Istituto Superiore di Sanità, Organismo
 Notificato 0373, certifica che il sistema di
 garanzia della qualità della produzione e/o
 della sterilizzazione attuato da

*The Istituto Superiore di Sanità, Notified Body
 0373, certifies that the quality assurance system
 for the production
 and/or sterilization enforced by*

MEUS S.r.l.

Sede Legale/ Registered Office:
Via Leonardo Da Vinci, 24/B - 35028 Piove di Sacco (PD) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/ Production Site: Via dell'Industria, 16 - 35020 Arzergrande (PD) Italia

per il dispositivo/i

for the device(s)

**MD 0115-Dispositivo monouso non attivo, sterile/Non - active disposable device,
 sterile (vedi allegato tecnico/ see technical sheet)***

è conforme ai requisiti applicabili della
 Direttiva Europea 93/42/CEE e successive
 modifiche ed integrazioni.

*is in compliance with the applicable
 requirements of Council Directive 93/42/EEC
 and subsequent modifications and integrations.*

Il Direttore dell'O.N.DI.CO.
 The Director of O.N.DI.CO.
 (Dr. Carmine Guarino)



* L'allegato tecnico è parte integrante del presente Certificato.
 The technical sheet is an integral part of this Certificate.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, production and distribution of
in vitro diagnostic products and consumption materials
for sample withdrawal, preparation and storage
as well as single-use medical devices**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

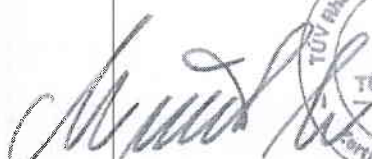
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2015-10-16
Certificate Registration No.: SX 60105391 0001
An audit was performed. Report No.: 21234760 001
This Certificate is valid until: 2018-10-15

Certification Body



Date 2015-10-16



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



Istituto Superiore di Sanità

Organismo Notificato 0373
Sezione Presso O.N.D.I.CO.
Notified Body 0373
Unit relating to O.N.D.I.CO.

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no..

QPS-0465-14

Addendum n°
addendum no.

//-//

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

MD 0115-Dispositivo monouso non attivo, sterile/Non – active disposable device, sterile

Nome prodotto
(Product name)

Tamponi, sterili

Tamponi, sterili in confezione singola

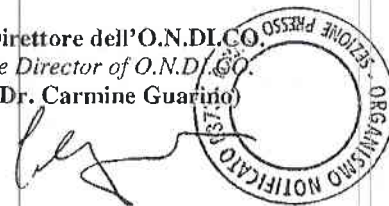
Tamponi sterili confezionati in provetta

*Tamponi, sterili confezionati in provetta contenenti terreno di trasposto**

*La marcatura CE si riferisce esclusivamente al tampone sterile e non all'intero sistema.

Il presente certificato sostituisce il certificato QPS 0453 14 del 09/03/2014;
This certificate supersedes the previous certificate QPS 0453 14 issued on 09/03/2014.

Il Direttore dell'O.N.D.I.CO.
The Director of O.N.D.I.CO.
(Dr. Carmine Guarino)





KABE
LABORTECHNIK

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers*/Händlers**:

Name and address of the manufacturer*/distributor**:

KABE LABORTECHNIK GmbH

Jägerhofstraße 17

51588 Nümbrecht-Elsenroth

Deutschland / Germany

Wir erklären in alleiniger Verantwortung* bzw. aufgrund der uns vom Hersteller vorliegenden Informationen**, dass die In-Vitro-Diagnostika der Produktgruppe /

We declare under our sole responsibility* respectively according to the information of the manufacturer** that the in-vitro-diagnostics of product group

kapillare Blutentnahmesysteme

- **Kapillarblutentnahmesystem (GK)***
- **kapillare Probenbehältnisse aus Kunststoff***
 - Blutgaskapillaren (BK)
 - Hämatokritkapillaren (HK)
 - end-to-end Kapillaren (EK)
- **kapillare Probenbehältnisse aus Glas****
 - Blutgaskapillaren (BK)
 - Hämatokritkapillaren (HK)
 - end-to-end Kapillaren (EK)
- Mikro-Kapillar-Pipetten mit Ringmarke (RM)

capillary blood collection systems

- **capillary blood collection system (GK)***
- **capillary sample containers made of plastic***
 - blood gas capillaries (BK)
 - haematocrit capillaries (HK)
 - end-to-end capillaries (EK)
- **capillary sample containers made of glass****
 - blood gas capillaries (BK)
 - haematocrit capillaries (HK)
 - end-to-end capillaries (EK)
- micro-capillary pipettes with ring mark (RM)

der Klasse / of class

Andere IVD-Produkte
Other IVD-devices

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

Konformitätsbewertungsverfahren:

Conformity assessment procedure:

Richtlinie 98/79/EG Anhang III

Directive 98/79/EC Annex III

Nümbrecht-Elsenroth, 26.07.2018

KABE LABORTECHNIK GmbH
Jägerhofstraße 17

D-51588 Nümbrecht-Elsenroth

☎ +49 (0) 2293 / 596


André Kolpe, Geschäftsführer / Managing director

CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

**DICHIARA
DECLARES**

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:

PROVETTE PER ANALISI CON VUOTO PRECALIBRATO VACUUM TEST TUBES



DISPOSITIVI STERILI – STERILE DEVICES

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- > Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.
Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.
- > I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.
The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.
- > Classificazione EDMA (Versione 2007): 1302808000 Coated tubes (Citrato, Heparin, etc.)
EDMA code (Version 2007): 1302808000 Coated tubes (Citrato, Heparin, etc.)
- > La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.
The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato / Released
Canelli, 07.01.2016

Duilio BEONO
Responsabile Assicurazione Qualità

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	DESCRIPTION
30001	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30002	Provette sottovuoto 3,0 ml, in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 3.0 ml, in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30003	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30004	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, without additive, white cap, interior sterile.
30020	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with clot activator, red cap, interior sterile.
30021	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with clot activator, red cap, interior sterile.
30022	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with clot activator, red cap, interior sterile.
30023	Provette sottovuoto 9,0 ml, in PET Ø16x100 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with clot activator, red cap, interior sterile.
30011	Provette sottovuoto 3,5 ml, in PET Ø13x75 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 3.5 ml, in PET, Ø13x75 mm, with clot activator + gel, red cap, interior sterile.
30012	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with clot activator + gel, red cap, interior sterile.
30013	Provette sottovuoto 8,0 ml, in PET Ø16x100 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 8.0 ml, in PET, Ø16x100 mm, with clot activator + gel, red cap, interior sterile.
30014	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con acceleratore + rapid gel, tappo rosso, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with clot activator + rapid gel, red cap, interior sterile.
30031	Provette sottovuoto 3,5 ml, in PET Ø13x75 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 3.5 ml, in PET, Ø13x75 mm, with clot activator + gel, gold cap, interior sterile.
30032	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with clot activator + gel, gold cap, interior sterile.
30033	Provette sottovuoto 8,0 ml, in PET Ø16x100 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 8.0 ml, in PET, Ø16x100 mm, with clot activator + gel, gold cap, interior sterile.
30200	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30200/1	Provette sottovuoto 1,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 1.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30201	Provette sottovuoto 3,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 3.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30202	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30203	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with K3 EDTA, lavender cap, interior sterile.
30204	Provette sottovuoto 9,0 ml, in PET Ø16x100 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with K3 EDTA, lavender cap, interior sterile.
30100	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30101	Provette sottovuoto 3,0 ml, in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 3.0 ml, in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30102	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30103	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with K2 EDTA, lavender cap, interior sterile.

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

Cod.	DESCRIZIONE	DESCRIPTION
30104	Provette sottovuoto 9,0 ml, in PET Ø16x100 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with K2 EDTA, lavender cap, interior sterile.
30300	Provette sottovuoto 1,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8% per VES, tappo nero, sterile interno.	Vacuum test tubes 1.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,2% for ESR, black cap, interior sterile.
30500	Provette sottovuoto 2,7 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 2.7 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,2%, light blue cap, interior sterile.
30501	Provette sottovuoto 3,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 3.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,2%, light blue cap, interior sterile.
30500/38	Provette sottovuoto 2,7 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 2.7 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,8%, light blue cap, interior sterile.
30501/38	Provette sottovuoto 3,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 3.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,8%, light blue cap, interior sterile.
30503	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,2%, light blue cap, interior sterile.
30503/38	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,8%, light blue cap, interior sterile.
30600	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Floruro + Sodio Eparina per glucosio, tappo grigio, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Fluoride + Sodium Heparin, gray cap, interior sterile.
30601	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Sodio Floruro + Sodio Eparina per glucosio, tappo grigio, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Sodium Fluoride + Sodium Heparin, gray cap, interior sterile.
30800	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Lithium Heparin, green cap, interior sterile.
30801	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Lithium Heparin, green cap, interior sterile.
30802	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with Lithium Heparin, green cap, interior sterile.
30900	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Litio Eparina + Gel, tappo verde chiaro, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Lithium Heparin + Gel, light green cap, interior sterile.
30901	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con Litio Eparina + Gel, tappo verde chiaro, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with Lithium Heparin + Gel, light green cap, interior sterile.
35100	Provette coniche sottovuoto 9,0 ml, in PET, Ø16x100 mm, senza additivo, tappo giallo, sterile interno.	Conical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, without additive, yellow cap, interior sterile.
35150	Provette cilindriche sottovuoto 9,0 ml, in PET, Ø16x100 mm, senza additivo, tappo giallo, sterile interno.	Cylindrical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, without additive, yellow cap, interior sterile.
35200	Provette coniche sottovuoto 9,0 ml, in PET, Ø16x100 mm, con preservante Acido Borico, tappo giallo, sterile interno.	Conical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with Boric Acid, yellow cap, interior sterile.
35250	Provette cilindriche sottovuoto 9,0 ml, in PET, Ø16x100 mm, con preservante Acido Borico, tappo giallo, sterile interno.	Cylindrical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with Boric Acid, yellow cap, interior sterile.
36005	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con K2 EDTA + Gel, tappo lavanda, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with K2 EDTA + Gel, lavender cap, interior sterile.

Dario BEONO
Responsabile Assicurazione Qualità