

AUTHORISATION LETTER

Wr. Neudorf, 06.02.2019

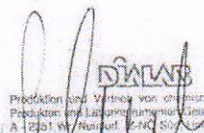
TO WHOM IT MAY CONCERN

We, **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**, headquarter in Austria, IZ-NÖ Süd, Hondastrasse Obj. M55, A-2351 Wr. Neudorf hereby declares that the below mentioned company is our official **representative** and is authorized to register, sell and distributor our products in the territory of Moldavia:

ECHIPAMED PLUS SRL
Valea Trandafirilor str., 24B, of.80,
MD-2001 Chisinau, Moldova

This certificate remains in force from 01.01.2019 until 31.12.2019 or is terminated during that period on the expiry of not less than 30 days' notice in writing given by either party to the other.

Signed for and on behalf of
DIALAB Produktion und Vertrieb von
chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H
Objekt M55
A-2351 Wr. Neudorf
AUSTRIA



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Christina Schneider
Export Manager



DECLARATION OF CONFORMITY

We



Dialab Produktion und Vertrieb von chemisch – technischen Produkten und
Laborinstrumenten Gesellschaft m. b. H.
IZ-NÖ Süd, Hondastrasse, Objekt M55
2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed
addendum "Devices other than those covered by Annex II (Clinical Chemistry)",
Rev.18 (8 pages),
classified as follows according to the directive on in vitro diagnostic medical
devices 98/79/EC:

Devices other than those covered by Annex II (Clinical Chemistry)

meet the applicable provisions of the European Directive 98 / 79 / EC for in-vitro-
diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on Conformity Assessment Procedures according
to Annex III of the aforesaid Directive.

This Declaration is valid until 2022-03-28

Wr. Neudorf, 2019-04-04



Marlene Ramsey
Managing Director

Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



CLINICAL CHEMISTRY

Reagents

	REF	CONT		REF	CONT
Adenosine Deaminase (ADA), Enzymatic, colorimetric	913816	6 x 25 ml			
	913813	3 x 25 ml			
	917810	3 x 10 ml			
Albumin, BCG	D97202B	1 x 1 L			
	D09550	4 x 250 ml			
	D97203	5 x 100 ml			
	D00204	5 x 50 ml			
	D00205	5 x 25 ml			
	D00206	5 x 10 ml			
	D51911	10 x 50 ml			
	D0401917	9 x 65 ml			
	DK0701	5 x 50 ml			
	DA0801	5 x 50 ml			
	DT1001	4 x 50 ml			
	DE1801	10 x 50 ml			
Alkaline Phosphatase, mod. IFCC	D03101B	1 x 1,25 L			
	D95564	5 x 100 ml			
	D95565	5 x 50 ml			
	D00523	5 x 25 ml			
	D00524	5 x 10 ml			
	D52911	10 x 50 ml			
	D0402917	5 x 62,5 ml			
	DK0703	5 x 50 ml			
	DA0803	5 x 50 ml			
	DT1003	4 x 62,5 ml			
	DE1803	2 x 62,5 ml			
Alkaline Phosphatase, opt. DGKC	D03102B	1 x 1,25 L			
	D95560	5 x 100 ml			
	D95561	5 x 50 ml			
	D00568	5 x 25 ml			
	D00569	5 x 10 ml			
	D53911	10 x 50 ml			
	D0403917	5 x 62,5 ml			
	DK0702	5 x 50 ml			
	DA0802	5 x 50 ml			
	DT1002	4 x 62,5 ml			
	DE1802	2 x 62,5 ml			
alpha-Amylase, mod. IFCC	D03103B	1 x 1,25 L			
	D94570	5 x 100 ml			
	D94571	5 x 50 ml			
	D00578	5 x 25 ml			
	D96569	5 x 10 ml			
	D54911	5 x 50 ml			
	D0406917	5 x 62,5 ml			
	DK0705	5 x 50 ml			
	DA0806	5 x 20 ml			
	DT1006	5 x 20 ml			
	DE1806	2 x 62,5 ml			
			alpha-Amylase, CNP-G3	397756B	1 x 1 L
				397758	5 x 100 ml
				397759	5 x 50 ml
				300760	5 x 25 ml
				396754	5 x 10 ml
				355911	10 x 50 ml
				D0405917	9 x 65 ml
				3K0704	5 x 50 ml
				3A0805	5 x 20 ml
				3T1005	5 x 20 ml
				3E1805	5 x 20 ml
			alpha-Amylase Pancreatic, ET-G7PNP	D00582	5 x 100 ml
				D94577	5 x 50 ml
				D00590	5 x 25 ml
				D96568	5 x 10 ml
				D56911	5 x 50 ml
				D0404917	5 x 50 ml
				DK0706	5 x 50 ml
				DA0807	5 x 20 ml
				DT1007	5 x 20 ml
				DE1807	1 x 62,5 ml
			Ammonia Enzymatic, UV	N08160	5 x 10 ml
				N49911	1 x 50 ml
				NA0804	5 x 20 ml
				NT1004	5 x 20 ml
				NE1804	5 x 20 ml
			Bile Acids, Enzymatic cycling	903110	5 x 100 ml
				903115	5 x 50 ml
				903120	5 x 25 ml
				903125	5 x 10 ml
				950911	5 x 50 ml
				90410917	4 x 60 ml
				9K0707	5 x 50 ml
				9A0808	4 x 20 ml
				9T1008	4 x 20 ml
				9E1808	2 x 50 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Bilirubin Auto Direct, DCA	D03104B	1 x 1,25 L
	D96543	5 x 100 ml
	D96544	5 x 50 ml
	D00547	5 x 25 ml
	D00548	5 x 10 ml
	D58911	10 x 50 ml
	D0408917	5 x 62,5 ml
	DK0708	5 x 50 ml
	DA0809	5 x 50 ml
	DT1009	4 x 62,5 ml
	DE1809	4 x 62,5 ml

Bilirubin Auto Total, DCA	D03105B	1 x 1,25 L
	D96531	5 x 100 ml
	D96532	5 x 50 ml
	D00535	5 x 25 ml
	D00536	5 x 10 ml
	D57911	10 x 50 ml
	D0409917	5 x 62,5 ml
	DK0709	5 x 50 ml
	DA0810	5 x 50 ml
	DT1010	4 x 62,5 ml
	DE1810	4 x 62,5 ml

Bilirubin Direct, Jendrassik Grof	103106B	1 x 1,04 L
	102002	5 x 100 ml
	102012	5 x 50 ml
	113022	5 x 25 ml

Bilirubin Total, Jendrassik Grof	103107B	1 x 1,04 L
	102001	5 x 100 ml
	102011	5 x 50 ml
	116021	5 x 25 ml

Bilirubin Direct/Total, Jendrassik Grof	103200	4 x 100 ml
	103210	4 x 50 ml
	116320	4 x 25 ml

Carbon Dioxide (CO ₂), PEP-C	N03122B	1 x 1 L
	N00043/20	5 x 50 ml
	N88911	5 x 50 ml
	N0414917	9 x 65 ml
	NK0712	5 x 50 ml
	NA0820	5 x 20 ml
	NT1020	5 x 20 ml
	NE1820	5 x 20 ml

Calcium, Arsenazo	D01372B	1 x 1 L
	D01376	5 x 100 ml
	D01375	5 x 50 ml
	D01377	5 x 25 ml
	D01378	5 x 10 ml
	D59911	10 x 50 ml
	D0412917	9 x 65 ml
	DK0710	5 x 50 ml
	DA0811	5 x 50 ml
	DT1011	4 x 50 ml
	DT1311	5 x 20 ml
	DE1811	5 x 20 ml

Calcium,
CPC

Chloride,
Mercuric thiocyanate

Cholesterol,
CHOD-PAP

Cholesterol HDL Direct,
Immunoinhibition

REF	CONT
D03108B	1 x 1,25 L
D99097	5 x 100 ml
D95098	5 x 50 ml
D00102	5 x 25 ml
D00100	5 x 10 ml
D60911	10 x 50 ml
D0413917	5 x 62,5 ml
DK0711	5 x 50 ml
DA0812	5 x 50 ml
DT1012	4 x 62,5 ml
DE1812	2 x 62,5 ml

D01222B	1 x 1 L
D01223	5 x 100 ml
D01225	5 x 50 ml
D01227	5 x 25 ml
D01228	5 x 10 ml
D61911	10 x 50 ml
D0415917	9 x 65 ml
DK0713	5 x 50 ml
DA0813	5 x 50 ml
DT1013	4 x 50 ml
DT1313	5 x 20 ml
DE1813	5 x 20 ml

D96112B	1 x 1 L
D08115	4 x 250 ml
D95116	5 x 100 ml
D98118	5 x 50 ml
D00119	5 x 25 ml
D00123	5 x 10 ml
D62911	10 x 50 ml
D0418917	9 x 65 ml
DK0714	5 x 50 ml
DA0814	5 x 50 ml
DT1014	4 x 50 ml
DE1814	10 x 50 ml

F03120B	1 x 1,25 L
F03100	5 x 100 ml
F03101	5 x 100 ml
F03115	5 x 50 ml
F03116	5 x 25 ml
F03117	5 x 10 ml
F16911	5 x 50 ml
F0416917	5 x 62,5 ml
FK0715	5 x 50 ml
FA0815	5 x 50 ml
FT1015	4 x 62,5 ml
FE1815	4 x 62,5 ml

Other Products (Clinical Chemistry), Rev.18



04.04.2019

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CK-NAC, <i>opt. DGKC / IFCC</i>	D03109B	1 x 1,25 L
	D00591	5 x 100 ml
	D94581	5 x 50 ml
	D00592	5 x 25 ml
	D98579	5 x 10 ml
	D64911	5 x 50 ml
	D0421917	5 x 62,5 ml
	DK0719	5 x 50 ml
	DA0819	5 x 50 ml
	DT1019	4 x 62,5 ml
	DE1819	2 x 62,5 ml

	REF	CONT
Copper, 3,5-DiBr-PAESA	507101B	1 x 1 L
	507140	5 x 25 ml
	545911	5 x 50 ml
	50447917	5 x 50 ml
	5K0720	5 x 50 ml
	5A0821	5 x 20 ml
	5T1221	4 x 50 ml
	5T1021	5 x 20 ml
	5E1821	5 x 20 ml
Creatinine, Enzymatic, PAP	D11112B	1 x 1 L
	D06420	4 x 100 ml
	D06430	4 x 50 ml
	D06440	4 x 25 ml
	D06450	4 x 10 ml
	D69911	4 x 50 ml
	D0411917	4 x 50 ml
	DK0721	5 x 40 ml
	DA0822	5 x 50 ml
	DT1022	4 x 50 ml
	DE1822	4 x 50 ml
Creatinine, mod. Jaffe	D03111B	1 x 1,25 L
	D95595	5 x 100 ml
	D10595	5 x 100 ml
	D00616	5 x 50 ml
	D00617	5 x 25 ml
	D00618	5 x 10 ml
	D66911	10 x 50 ml
	D0422917	5 x 62,5 ml
	DK0722	5 x 50 ml
	DA0823	5 x 50 ml
	DT1023	4 x 62,5 ml
	DE1823	4 x 62,5 ml
Ethanol, Enzymatic, UV	D07830	5 x 50 ml
	D07840	5 x 25 ml
	D07850	5 x 10 ml
	D67911	5 x 50 ml
	D0407917	5 x 50 ml
	DK0723	5 x 50 ml
	DA0824	5 x 20 ml
	DT1024	5 x 20 ml
	DE1824	2 x 62,5 ml

Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



Fructosamine, NBT	REF	CONT
	310110B	1 x 1 L
	310140	2 x 20 ml
	310144	4 x 20 ml

G6PDH, UV, kinetic	Y04500	10 x 18 ml
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Gamma GT, Szasz, standardized to IFCC	D03113B	1 x 1,25 L
	D00628	5 x 100 ml
	D95604	5 x 50 ml
	D00629	5 x 25 ml
	D98631	5 x 10 ml
	D68911	5 x 50 ml
	D0423917	5 x 62,5 ml
	DK0724	5 x 50 ml
	DA0825	5 x 50 ml
	DT1025	4 x 62,5 ml
	DE1825	2 x 62,5 ml

GLDH, DGKC	D03774	5 x 100 ml
	D03773	5 x 50 ml
	D03775	5 x 25 ml
	D03776	5 x 10 ml
	D03911	5 x 50 ml
	D0424917	5 x 50 ml
	DK0725	5 x 50 ml
	DA0826	5 x 20 ml
	DT1026	5 x 20 ml
	DE1826	1 x 62,5 ml

Glucose, GOD-PAP	D95218B	1 x 1 L
	D08220	4 x 250 ml
	D00221	5 x 100 ml
	D98221	5 x 50 ml
	D00223	5 x 25 ml
	D00224	5 x 10 ml
	D70911	10 x 50 ml
	D0425917	9 x 65 ml
	DK0726	5 x 50 ml
	DA0827	5 x 50 ml
	DT1027	4 x 50 ml
	DE1827	10 x 50 ml

Glucose, Hexokinase	D03114B	1 x 1,25 L
	D96226	5 x 100 ml
	D96227	5 x 50 ml
	D00632	5 x 25 ml
	D00637	5 x 10 ml
	D71911	5 x 50 ml
	D0426917	5 x 62,5 ml
	DK0727	5 x 50 ml
	DA0828	5 x 50 ml
	DT1028	4 x 62,5 ml
	DE1828	8 x 62,5 ml

GOT (AST),
mod. IFCC

GPT (ALT),
mod. IFCC

alpha-HBDH,
opt. DGKC

Homocysteine,
Enzymatic cycling

REF	CONT
D03115B	1 x 1,25 L
D94610	5 x 100 ml
D10610	5 x 100 ml
D98616	5 x 50 ml
D10616	5 x 50 ml
D00678	5 x 25 ml
D98617	5 x 10 ml
D72911	10 x 50 ml
D0427917	5 x 62,5 ml
DK0728	5 x 50 ml
DA0829	5 x 50 ml
DT1029	4 x 62,5 ml
DE1829	4 x 62,5 ml

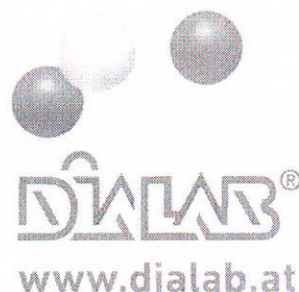
D03116B	1 x 1,25 L
D94620	5 x 100 ml
D10620	5 x 100 ml
D98624	5 x 50 ml
D10624	5 x 50 ml
D00640	5 x 25 ml
D98625	5 x 10 ml
D73911	10 x 50 ml
D0428917	5 x 62,5 ml
DK0729	5 x 50 ml
DA0830	5 x 50 ml
DT1030	4 x 62,5 ml
DE1830	4 x 62,5 ml

D96635	5 x 50 ml
D00642	5 x 25 ml
D00643	5 x 10 ml
D74911	5 x 50 ml
D0429917	5 x 62,5 ml
DK0730	5 x 50 ml
DA0831	5 x 20 ml
DT1031	5 x 20 ml
DE1831	1 x 62,5 ml

908510	4 x 20 ml
908520	4 x 10 ml
992911	1 x 39 ml
9A0849	4 x 20 ml
9T1049	4 x 20 ml
9E1849	2 x 39 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Hemoglobin Total, Cyanmethemoglobin	Y04704B	1 x 1 L
	Y04701	5 x 100 ml
	Y04702	5 x 50 ml
beta-Hydroxybutyrate Enzymatic, UV	D18027	5 x 25 ml
	D18028	5 x 10 mL
	D42911	1 x 50 ml
	DA1832	5 x 20 ml
	DT1832	5 x 20 ml
	DE1832	1 x 62,5 ml
Iron, Ferene	D03118B	1 x 1,25 L
	D01103	5 x 100 ml
	D01104	5 x 50 ml
	D01105	5 x 25 ml
	D01106	5 x 10 ml
	D91911	10 x 50 ml
	D0430917	5 x 62,5 ml
	DK0732	5 x 50 ml
	DA0833	5 x 50 ml
	DT1033	4 x 62,5 ml
Lactate Enzymatic, UV	DE1833	2 x 62,5 ml
	D08110B	1 x 1 L
	D08130	5 x 50 ml
	D08140	5 x 25 ml
	D14150	5 x 10 ml
	D75911	5 x 50 ml
	D0445917	5 x 50 ml
	DK1431	5 x 50 ml
	DA0834	5 x 20 ml
	DT1034	5 x 20 ml
LDH-L, IFCC	DE1834	2 x 62,5 ml
	D03300B	1 x 1,25 L
	D00662	5 x 100 ml
	D00663	5 x 50 ml
	D00664	5 x 25 ml
	D00665	5 x 10 ml
	D89911	5 x 50 ml
	D0431917	5 x 62,5 ml
	DK0733	5 x 50 ml
	DA0835	5 x 50 ml
LDH-P, opt. DGKC	DT1035	4 x 62,5 ml
	DE1835	2 x 62,5 ml
	D03119B	1 x 1,25 L
	D00656	5 x 100 ml
	D94651	5 x 50 ml
	D00657	5 x 25 ml
	D00658	5 x 10 ml
	D76911	5 x 50 ml
	D0432917	5 x 62,5 ml
	DK0734	5 x 50 ml
	DA0836	5 x 50 ml
	DT1036	4 x 62,5 ml
	DE1836	2 x 62,5 ml

	REF	CONT
Lipase, Enzymatic, colorimetric	D01441	5 x 50 ml
	D01440	5 x 25 ml
	D01443	5 x 10 ml
	D44911	5 x 50 ml
	D0433917	5 x 50 ml
	DK0735	5 x 50 ml
	DA0837	5 x 20 ml
	DT1037	5 x 20 ml
Lithium Enzymatic	DE1837	2 x 62,5 ml
	910210	3 x 20 ml
	9A0850	3 x 20 ml
	9T1050	3 x 20 ml
	947911	1 x 60 ml
Magnesium, Xylidyl blue	9E1850	1 x 60 ml
	D01241B	1 x 1 L
	D01243	5 x 100 ml
	D01245	5 x 50 ml
	D01256	5 x 25 ml
	D01246	5 x 10 ml
	D78911	10 x 50 ml
	D0434917	9 x 65 ml
	DK0736	5 x 50 ml
	DA0838	5 x 50 ml
NEFA, ACOD-PAP	DT1038	4 x 50 ml
	DT1338	5 x 20 ml
	DE1838	5 x 20 ml
	D07940	5 x 25 ml
	D07950	5 x 10 ml
	D77911	1 x 50 ml
	D0443917	5 x 50 ml
	DK0948	5 x 50 ml
	DA0839	5 x 20 ml
	DT1039	5 x 20 ml
Phosphorus Inorganic, Molybdate	DE1839	1 x 62,5 ml
	D00359B	1 x 1 L
	D00361	5 x 100 ml
	D00362	5 x 50 ml
	D00363	5 x 25 ml
	D00364	5 x 10 ml
	D85911	10 x 50 ml
	D0435917	9 x 65 ml
	DK0737	5 x 50 ml
	DA0840	5 x 50 ml
	DT1040	4 x 50 ml
	DT1340	5 x 20 ml
	DE1840	5 x 20 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Potassium, Enzymatic	914105	5 x 100 ml
	914106	5 x 50 ml
	914107	5 x 25 ml
	910110	5 x 10 ml
	948911	1 x 50 ml
	9A0851	5 x 20 ml
	9T1051	5 x 20 ml
	9E1851	2 x 62,5 ml

Protein Total, Biuret	D03120B	1 x 1,25 ml
	D95680	5 x 100 ml
	D00685	5 x 50 ml
	D00686	5 x 25 ml
	D00687	5 x 10 ml
	D80911	10 x 50 ml
	D0437917	5 x 62,5 ml
	DK0738	5 x 50 ml
	DA0841	5 x 50 ml
	DT1041	4 x 62,5 ml
	DE1841	8 x 62,5 ml

Protein Total Mono, Biuret	D12681B	1 x 1 L
	D12680	5 x 100 ml
	D13685	5 x 50 ml
	D13686	5 x 25 ml
	D13687	5 x 10 ml
	D43911	10 x 50 ml
	D0448917	9 x 65 ml
	DA1353	5 x 50 ml
	DT1353	4 x 50 ml
	DK1346	5 x 50 ml
	DE1853	10 x 50 ml

Protein Total in Urine/CSF, Pyrogallol red	D03127B	1 x 1 L
	D03200	5 x 25 ml
	D79911	5 x 50 ml
	D0436917	9 x 65 ml
	DK0739	5 x 50 ml
	DA1042	5 x 20 ml
	DT1042	5 x 20 ml
	DE1842	5 x 20 ml

Triglycerides, GPO-PAP	D98386B	1 x 1 L
	D08388	4 x 250 ml
	D00389	5 x 100 ml
	D96388	5 x 50 ml
	D00390	5 x 25 ml
	D98390	5 x 10 ml
	D81911	10 x 50 ml
	D0438917	9 x 65 ml
	DK0740	5 x 50 ml
	DA0843	5 x 50 ml
	DT1043	4 x 50 ml
	DE1843	10 x 50 ml

	REF	CONT
Sodium, Enzymatic	914605	5 x 100 ml
	914607	6 x 25 ml
	909610	3 x 20 ml
	990911	1 x 60 ml
	9A0852	3 x 20 ml
	9T1052	3 x 20 ml
	9E1852	2 x 60 ml

UIBC, Ferene	D07300B	1 x 12,5 L
	D07310B	1 x 1 L
	D07320	5 x 100 ml
	D07330	5 x 50 ml
	D07340	5 x 25 ml
	D07350	5 x 10 ml
	D86911	5 x 50 ml
	D0444917	5 x 62,5 ml
	D1444917	350 ml
	DK0741	5 x 50 ml
	DA0844	5 x 50 ml
	DT1044	4 x 62,5 ml
	DE1844	2 x 62,5 ml

Urea UV Auto, Urease/GLDH	D03121B	1 x 1,25 L
	D95704	5 x 100 ml
	D10704	5 x 100 ml
	D98707	5 x 50 ml
	D10707	5 x 50 ml
	D00715	5 x 25 ml
	D00716	5 x 10 ml
	D82911	10 x 50 ml
	D0439917	5 x 62,5 ml
	DK0742	5 x 50 ml
	DA0845	5 x 50 ml
	DT1045	4 x 62,5 ml
	DE1845	4 x 62,5 ml

Urea, Urease/colorimetric	402999	5 x 100 ml
	413925	6 x 25 ml
Uric Acid AOX, Enzymatic, colorimetric	D94710	5 x 100 ml
	D98714	5 x 50 ml
	D00719	5 x 25 ml
	D00720	5 x 10 ml
	D84911	10 x 50 ml
	D0440917	5 x 62,5 ml
	DK0743	5 x 50 ml
	DA0846	5 x 50 ml
	DT1046	4 x 62,5 ml
	E1846	8 x 62,5 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Uric Acid TBHBA, Enzymatic, colorimetric	D03123B	1 x 1,25 L
	D95459	5 x 100 ml
	D10459	5 x 100 ml
	D98461	5 x 50 ml
	D10461	5 x 50 ml
	D00463	5 x 25 ml
	D00464	5 x 10 ml
	D83911	10 x 50 ml
	D0441917	5 x 62,5 ml
	DK0744	5 x 50 ml
	DA0847	5 x 50 ml
	DT1047	4 x 62,5 ml
	DE1847	8 x 62,5 ml
Zinc 5-Br-PAPS	507201B	1 x 1 L
	507240	5 x 25 ml
	587911	5 x 50 ml
	50446917	5 x 50 ml
	5K0745	5 x 50 ml
	5A0848	5 x 20 ml
	5T1048	5 x 20 ml
	5E1848	5 x 20 ml

	REF	CONT
Auxiliary Reagents, Supplements and Additives		
	REF	CONT
G6PDH Lyse Reagent	Y04550LV	1 x 60 ml
Pyridoxal-5'-Phosphate	D96361	1 x 4 ml
Cholesterol HDL Precipitant	D96122B	1 x 1 L
	D14125	5 x 100 ml
	D00127	5 x 50 ml
	D00142	5 x 25 ml
	D00129	5 x 10 ml
Cholesterol LDL Precipitant	D13136	5 x 100 ml
	D13137	5 x 50 ml
	D13138	5 x 25 ml
	D13139	5 x 10 ml



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Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



Calibrators

	REF	CONT
Diacal Auto	D98485	5 x 3 ml
	D98485SV	1 x 3 ml
Diacal Lipids	D13585SV	1 x 2 ml
Diacal CK-MB	D13595	5 x 1 ml
	D13595SV	1 x 1 ml
ADA Calibrator	913870SV	1 x 1 ml
G6PDH Calibrator	Y17565SV	1 x 0,5 ml
Homocysteine Calibrator Set (5 levels)	908550	5 x 1 ml
Ethanol Calibrator/Control Set	Z05880	4 x 1 ml
HDL-Cholesterol Calibrator	F03710SV	1 x 3 ml
LDL-Cholesterol Calibrator	F03711SV	1 x 1 ml
Hemoglobin Total Calibrator	Y04705SV	1 x 2 ml

Standards

	REF	CONT		REF	CONT
Albumin Standard	D95555	1 x 3 ml	Lithium Standard Set (3 levels)	910280	3 x 3 ml
Ammonia Standard	Y08310SV	1 x 5 ml	Lithium Standard Set (5 levels)	910285	5 x 3 ml
Bile Acids Standard	903210	1 x 3 ml	Magnesium Standard	D95339	1 x 3 ml
Calcium Standard	D95094	1 x 3 ml	NEFA Standard	D07963SV	1 x 3 ml
Chloride Standard	D95108	1 x 3 ml	Phosphorus Standard	D95362	1 x 3 ml
Cholesterol Standard	D95114	1 x 3 ml	Potassium Standard Set (2 levels)	910180	2 x 3 ml
CO2 Standard	D06520SV	1 x 3 ml	Protein Total Standard	D94683	1 x 3 ml
Copper Standard	507163SV	1 x 3 ml	Protein Total in Urine/CSF Standard	D03600	1 x 3 ml
Creatinine Standard	D94592	1 x 3 ml	Sodium Standard Set (2 levels)	909680	2 x 3 ml
Glucose Standard	D95223	1 x 3 ml	Triglycerides Standard	D95380	1 x 3 ml
beta-Hydroxybutyrate Standard	D10090SV	1 x 3 ml	Urea Standard	D95706	1 x 3 ml
Iron Standard	D95305	1 x 3 ml	Uric Acid Standard	D94708	1 x 3 ml
			Zinc Standard	507263SV	1 x 3 ml

Controls

	REF	CONT		REF	CONT
Diacon N	D98481	12 x 5 ml	Diacon Urine Level 1	D08581	12 x 5 ml
	D14481	5 x 5 ml		D08581SV	1 x 5 ml
	D98481SV	1 x 5 ml	Diacon Urine Level 2	D08582	12 x 5 ml
Diacon P	D98482	12 x 5 ml		D08582SV	1 x 5 ml
	D14482	5 x 5 ml	ADA Control Set (2 levels)	913880	2 x 1 ml
	D98482SV	1 x 5 ml	Ammonia Control Set (2 levels)	Y08330	2 x 5 ml
Diacon Lipids	D99486	3 x 3 ml	G6PDH Control Set (3 levels)	Y17560	6 x 0,5 ml
	D99486SV	1 x 3 ml	Hemoglobin Total Control Set (3 levels)	Y04706	6 x 2 ml
Diacon Lipids High	D11487	3 x 3 ml			
	D11487SV	1 x 3 ml	Homocysteine Control Set (4 levels)	905620	4 x 1 ml
CO2 Control	D16525	3 x 3 ml	Lithium Control Set (2 levels)	910290	2 x 3 ml
	D16525SV	1 x 3 ml	Potassium Control Set (2 levels)	910190	2 x 3 ml

