

AUTHORISATION LETTER

Wr. Neudorf, 06.02.2019

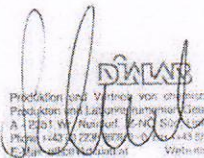
TO WHOM IT MAY CONCERN

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



DIALAB
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Christina Schneider
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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkKS
 Deutsche
 Akkreditierungsstelle
 D-ZM-11321-01-00



Product Service

Certificate

No. Q5 026709 0009 Rev. 00

Holder of Certificate: **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**
 IZ-NOE Sued
 Hondastrasse, Objekt M55
 2351 Wr. Neudorf
 AUSTRIA

Facility(ies): DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
 IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

Certification Mark:



Scope of Certificate: Design and development, production and distribution of reagents and reagent products for in-vitro diagnostics as well as distribution of instruments for in-vitro diagnostics including accessories

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
 DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713146001
Valid from: 2019-03-29
Valid until: 2022-03-28

Date, 2019-03-28 Stefan Preiß



Addendum to the Declaration of Conformity of Devices for List A, Annex II (mdc)

ABO and Rhesus Typing	REF	CONT	LOT
Anti-A, monoclonal	B05405	10 mL	600129-B3, 600134-A4, 600135-A3, 600136-C2, 600136-H2, 600136-WW
CE-Certificate No.:	D4000100004 and D4000100005		

Anti-B, monoclonal	B05406	10 mL	610154-A2, 610156-B3, 610159-A4, 610159-C3, 610160-A2, 610161-B2, 610164-H3
CE-Certificate No.:	D4000100004 and D4000100005		

Anti-AB, monoclonal	B05407	10 mL	620116-B3, 620119-C2, 620121-C2, 620124-B3, 620125-F3
CE-Certificate No.:	D4000100004 and D4000100005		

Anti-D (IgM/IgG), monoclonal	B05408	10 mL	740156-B2, 740156-B3, 740162-A2, 740162-B4, 740162-D2, 740163-F3, 740163-H2
CE-Certificate No.:	D4000100004 and D4000100005		

Anti-D Negative Control	B09936	10 mL	650293-B7
CE-Certificate No.:	D4000100004 and D4000100005		

EC DECLARATION OF CONFORMITY



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

We

declare, on our own responsibility, that our products specified in the enclosed addendum "Devices of List A, Annex II (mdc), Rev.06 (1 page)",
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices of List A, Annex II

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 IV, section 3 and 4 of the aforesaid Directive in cooperation with the notified body

mdc medical device certification GmbH, code no. 0483
Kriegerstraße 6 / 70191 Stuttgart / Germany

This Declaration is valid until 2021-04-24.



DI Marlene Ramsey
Managing Director

Wf. Neudorf, 2017-12-21

Devices of List A, Annex II (mdc), Rev.06

2017-12-21

Page 1 of 1



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:

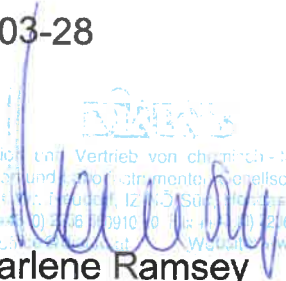
Devices other than those covered by Annex II (Clinical Chemistry)

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



Produktion und Vertrieb von chemisch – technischen
Produkten und Laborinstrumenten Gesellschaft m. b. H.
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Marlene Ramsey
Managing Director

CLINICAL CHEMISTRY

Reagents

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

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



	REF	CONT		REF	CONT		
Bilirubin Auto Direct, DCA	D03104B	1 x 1,25 L	Calcium, CPC	D03108B	1 x 1,25 L		
	D96543	5 x 100 ml		D99097	5 x 100 ml		
	D96544	5 x 50 ml		D95098	5 x 50 ml		
	D00547	5 x 25 ml		D00102	5 x 25 ml		
	D00548	5 x 10 ml		D00100	5 x 10 ml		
	D58911	10 x 50 ml		D60911	10 x 50 ml		
	D0408917	5 x 62,5 ml		D0413917	5 x 62,5 ml		
	DK0708	5 x 50 ml		DK0711	5 x 50 ml		
	DA0809	5 x 50 ml		DA0812	5 x 50 ml		
	DT1009	4 x 62,5 ml		DT1012	4 x 62,5 ml		
	DE1809	4 x 62,5 ml		DE1812	2 x 62,5 ml		
	Bilirubin Auto Total, DCA	D03105B		1 x 1,25 L	Chloride, Mercuric thiocyanate	D01222B	1 x 1 L
		D96531		5 x 100 ml		D01223	5 x 100 ml
D96532		5 x 50 ml	D01225	5 x 50 ml			
D00535		5 x 25 ml	D01227	5 x 25 ml			
D00536		5 x 10 ml	D01228	5 x 10 ml			
D57911		10 x 50 ml	D61911	10 x 50 ml			
D0409917		5 x 62,5 ml	D0415917	9 x 65 ml			
DK0709		5 x 50 ml	DK0713	5 x 50 ml			
DA0810		5 x 50 ml	DA0813	5 x 50 ml			
DT1010		4 x 62,5 ml	DT1013	4 x 50 ml			
DE1810		4 x 62,5 ml	DT1313	5 x 20 ml			
Bilirubin Direct, Jendrassik Grof	103106B	1 x 1,04 L	DE1813	5 x 20 ml			
	102002	5 x 100 ml	Cholesterol, CHOD-PAP	D96112B	1 x 1 L		
	102012	5 x 50 ml		D08115	4 x 250 ml		
	113022	5 x 25 ml		D95116	5 x 100 ml		
Bilirubin Total, Jendrassik Grof	103107B	1 x 1,04 L		D98118	5 x 50 ml		
	102001	5 x 100 ml		D00119	5 x 25 ml		
	102011	5 x 50 ml		D00123	5 x 10 ml		
	116021	5 x 25 ml		D62911	10 x 50 ml		
Bilirubin Direct/Total, Jendrassik Grof	103200	4 x 100 ml		D0418917	9 x 65 ml		
	103210	4 x 50 ml		DK0714	5 x 50 ml		
	116320	4 x 25 ml		DA0814	5 x 50 ml		
Carbon Dioxide (CO ₂), PEP-C	N03122B	1 x 1 L		DT1014	4 x 50 ml		
	N00043/20	5 x 50 ml	DE1814	10 x 50 ml			
	N88911	5 x 50 ml	Cholesterol HDL Direct, Immuno-inhibition	F03120B	1 x 1,25 L		
	N0414917	9 x 65 ml		F03100	5 x 100 ml		
	NK0712	5 x 50 ml		F03101	5 x 100 ml		
	NA0820	5 x 20 ml		F03115	5 x 50 ml		
	NT1020	5 x 20 ml		F03116	5 x 25 ml		
	NE1820	5 x 20 ml		F03117	5 x 10 ml		
	Calcium, Arsenazo	D01372B		1 x 1 L	F16911	5 x 50 ml	
D01376		5 x 100 ml		F0416917	5 x 62,5 ml		
D01375		5 x 50 ml		FK0715	5 x 50 ml		
D01377		5 x 25 ml		FA0815	5 x 50 ml		
D01378		5 x 10 ml		FT1015	4 x 62,5 ml		
D59911		10 x 50 ml	FE1815	4 x 62,5 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						

	REF	CONT
Cholesterol LDL Direct, <i>Enzymatic selective protection</i>	F05126B	1 x 1,25 L
	F05365	5 x 50 ml
	F05366	5 x 25 ml
	F05367	5 x 10 ml
	F19911	5 x 50 ml
	F14911	1 x 50 ml
	F0417917	5 x 20 ml
	F0443917	5 x 62,5 ml
	FK0716	5 x 50 ml
	FA0816	5 x 20 ml
	FT1016	5 x 20 ml
	FT1616	4 x 62,5 ml
	FE1816	2 x 62,5 ml

	REF	CONT
Cholinesterase, <i>opt. DGKC</i>	D07710B	1 x 1,25 L
	D07720	5 x 100 ml
	D07730	5 x 50 ml
	D07740	5 x 25 ml
	D07750	5 x 10 ml
	D63911	5 x 50 ml
	D0419917	5 x 62,5 ml
	DK0717	5 x 50 ml
	DA0817	5 x 50 ml
	DT1017	4 x 62,5 ml
DE1817	2 x 62,5 ml	

	REF	CONT
CK-MB, <i>opt. DGKC / IFCC</i>	D10580B	1 x 12,5 L
	D10582B	1 x 1 L
	D10585	5 x 100 ml
	D10586	5 x 50 ml
	D10587	5 x 25 ml
	D10588	5 x 10 ml
	D35911	5 x 50 ml
	D0450917	5 x 62,5 ml
	DK1018	5 x 50 ml
	DA1018	5 x 20 ml
	DT1018	5 x 20 ml
	DE1818	2 x 62,5 ml
	D00589	5 x 25 ml
	D98589	5 x 10 ml

	REF	CONT
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, <i>3,5-DiBr-PAESA</i>	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	

	REF	CONT
Creatinine, <i>Enzymatic, PAP</i>	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	

	REF	CONT
Creatinine, <i>mod. Jaffe</i>	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

	REF	CONT
Ethanol, <i>Enzymatic, UV</i>	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)



	REF	CONT		REF	CONT	
Fructosamine, NBT	310110B	1 x 1 L	GOT (AST), mod. IFCC	D03115B	1 x 1,25 L	
	310140	2 x 20 ml		D94610	5 x 100 ml	
	310144	4 x 20 ml		D10610	5 x 100 ml	
G6PDH, UV, kinetic	Y04500	10 x 18 ml		D98616	5 x 50 ml	
				D10616	5 x 50 ml	
Gamma GT, Szasz, standardized to IFCC	D03113B	1 x 1,25 L		D00678	5 x 25 ml	
	D00628	5 x 100 ml		D98617	5 x 10 ml	
	D95604	5 x 50 ml		D72911	10 x 50 ml	
	D00629	5 x 25 ml		D0427917	5 x 62,5 ml	
	D98631	5 x 10 ml		DK0728	5 x 50 ml	
	D68911	5 x 50 ml		DA0829	5 x 50 ml	
	D0423917	5 x 62,5 ml		DT1029	4 x 62,5 ml	
	DK0724	5 x 50 ml		DE1829	4 x 62,5 ml	
	DA0825	5 x 50 ml		GPT (ALT), mod. IFCC	D03116B	1 x 1,25 L
	DT1025	4 x 62,5 ml			D94620	5 x 100 ml
DE1825	2 x 62,5 ml	D10620	5 x 100 ml			
GLDH, DGKC	D03774	5 x 100 ml	D98624		5 x 50 ml	
	D03773	5 x 50 ml	D10624		5 x 50 ml	
	D03775	5 x 25 ml	D00640		5 x 25 ml	
	D03776	5 x 10 ml	D98625		5 x 10 ml	
	D03911	5 x 50 ml	D73911		10 x 50 ml	
	D0424917	5 x 50 ml	D0428917		5 x 62,5 ml	
	DK0725	5 x 50 ml	DK0729		5 x 50 ml	
	DA0826	5 x 20 ml	DA0830	5 x 50 ml		
	DT1026	5 x 20 ml	DT1030	4 x 62,5 ml		
	DE1826	1 x 62,5 ml	DE1830	4 x 62,5 ml		
Glucose, GOD-PAP	D95218B	1 x 1 L	alpha-HBDH, opt. DGKC	D96635	5 x 50 ml	
	D08220	4 x 250 ml		D00642	5 x 25 ml	
	D00221	5 x 100 ml		D00643	5 x 10 ml	
	D98221	5 x 50 ml		D74911	5 x 50 ml	
	D00223	5 x 25 ml		D0429917	5 x 62,5 ml	
	D00224	5 x 10 ml		DK0730	5 x 50 ml	
	D70911	10 x 50 ml		DA0831	5 x 20 ml	
	D0425917	9 x 65 ml		DT1031	5 x 20 ml	
	DK0726	5 x 50 ml		DE1831	1 x 62,5 ml	
	DA0827	5 x 50 ml		Homocysteine, Enzymatic cycling	908510	4 x 20 ml
	DT1027	4 x 50 ml			908520	4 x 10 ml
	DE1827	10 x 50 ml			992911	1 x 39 ml
Glucose, Hexokinase	D03114B	1 x 1,25 L	9A0849		4 x 20 ml	
	D96226	5 x 100 ml	9T1049		4 x 20 ml	
	D96227	5 x 50 ml	9E1849		2 x 39 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					

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



	REF	CONT		REF	CONT
Hemoglobin Total, <i>Cyanmethemoglobin</i>	Y04704B	1 x 1 L			
	Y04701	5 x 100 ml			
	Y04702	5 x 50 ml			
beta-Hydroxybutyrate <i>Enzymatic, UV</i>	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, <i>Ferene</i>	D03118B	1 x 1,25 L	<i>Lipase, Enzymatic, colorimetric</i>	D01441	5 x 50 ml
	D01103	5 x 100 ml		D01440	5 x 25 ml
	D01104	5 x 50 ml		D01443	5 x 10 ml
	D01105	5 x 25 ml		D44911	5 x 50 ml
	D01106	5 x 10 ml		D0433917	5 x 50 ml
	D91911	10 x 50 ml		DK0735	5 x 50 ml
	D0430917	5 x 62,5 ml		DA0837	5 x 20 ml
	DK0732	5 x 50 ml		DT1037	5 x 20 ml
	DA0833	5 x 50 ml		DE1837	2 x 62,5 ml
	DT1033	4 x 62,5 ml			
DE1833	2 x 62,5 ml	<i>Lithium Enzymatic</i>	910210	3 x 20 ml	
			9A0850	3 x 20 ml	
			9T1050	3 x 20 ml	
			947911	1 x 60 ml	
			9E1850	1 x 60 ml	
Lactate <i>Enzymatic, UV</i>	D08110B	1 x 1 L	<i>Magnesium, Xylidyl blue</i>	D01241B	1 x 1 L
	D08130	5 x 50 ml		D01243	5 x 100 ml
	D08140	5 x 25 ml		D01245	5 x 50 ml
	D14150	5 x 10 ml		D01256	5 x 25 ml
	D75911	5 x 50 ml		D01246	5 x 10 ml
	D0445917	5 x 50 ml		D78911	10 x 50 ml
	DK1431	5 x 50 ml		D0434917	9 x 65 ml
	DA0834	5 x 20 ml		DK0736	5 x 50 ml
	DT1034	5 x 20 ml		DA0838	5 x 50 ml
	DE1834	2 x 62,5 ml		DT1038	4 x 50 ml
LDH-L, <i>IFCC</i>	D03300B	1 x 1,25 L	<i>NEFA, ACOD-PAP</i>	DT1338	5 x 20 ml
	D00662	5 x 100 ml		DE1838	5 x 20 ml
	D00663	5 x 50 ml		D07940	5 x 25 ml
	D00664	5 x 25 ml		D07950	5 x 10 ml
	D00665	5 x 10 ml		D77911	1 x 50 ml
	D89911	5 x 50 ml		D0443917	5 x 50 ml
	D0431917	5 x 62,5 ml		DK0948	5 x 50 ml
	DK0733	5 x 50 ml		DA0839	5 x 20 ml
	DA0835	5 x 50 ml		DT1039	5 x 20 ml
	DT1035	4 x 62,5 ml		DE1839	1 x 62,5 ml
DE1835	2 x 62,5 ml				
LDH-P, <i>opt. DGKC</i>	D03119B	1 x 1,25 L	<i>Phosphorus Inorganic, Molybdate</i>	D00359B	1 x 1 L
	D00656	5 x 100 ml		D00361	5 x 100 ml
	D94651	5 x 50 ml		D00362	5 x 50 ml
	D00657	5 x 25 ml		D00363	5 x 25 ml
	D00658	5 x 10 ml		D00364	5 x 10 ml
	D76911	5 x 50 ml		D85911	10 x 50 ml
	D0432917	5 x 62,5 ml		D0435917	9 x 65 ml
	DK0734	5 x 50 ml		DK0737	5 x 50 ml
	DA0836	5 x 50 ml		DA0840	5 x 50 ml
	DT1036	4 x 62,5 ml		DT1040	4 x 50 ml
DE1836	2 x 62,5 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		REF	CONT			
Potassium, <i>Enzymatic</i>	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, <i>Biuret</i>	D03120B				1 x 1,25 ml		Sodium, <i>Enzymatic</i>
D95680		5 x 100 ml	914607	6 x 25 ml				
D00685		5 x 50 ml	909610	3 x 20 ml				
D00686		5 x 25 ml	990911	1 x 60 ml				
D00687		5 x 10 ml	9A0852	3 x 20 ml				
D80911		10 x 50 ml	9T1052	3 x 20 ml				
D0437917		5 x 62,5 ml	9E1852	2 x 60 ml				
DK0738		5 x 50 ml	UIBC, <i>Ferene</i>	D07300B	1 x 12,5 L			
DA0841		5 x 50 ml		D07310B	1 x 1 L			
DT1041		4 x 62,5 ml		D07320	5 x 100 ml			
DE1841		8 x 62,5 ml		D07330	5 x 50 ml			
Protein Total Mono, <i>Biuret</i>		D12681B		1 x 1 L	D07340	5 x 25 ml		
		D12680		5 x 100 ml	D07350	5 x 10 ml		
	D13685	5 x 50 ml		D86911	5 x 50 ml			
	D13686	5 x 25 ml		D0444917	5 x 62,5 ml			
	D13687	5 x 10 ml		D1444917	350 ml			
	D43911	10 x 50 ml		DK0741	5 x 50 ml			
	D0448917	9 x 65 ml		DA0844	5 x 50 ml			
	DA1353	5 x 50 ml		DT1044	4 x 62,5 ml			
	DT1353	4 x 50 ml		DE1844	2 x 62,5 ml			
	DK1346	5 x 50 ml	Urea UV Auto, <i>Urease/GLDH</i>	D03121B	1 x 1,25 L			
	DE1853	10 x 50 ml		D95704	5 x 100 ml			
	Protein Total in Urine/CSF, <i>Pyrogallol red</i>	D03127B		1 x 1 L	D10704	5 x 100 ml		
		D03200		5 x 25 ml	D98707	5 x 50 ml		
D79911		5 x 50 ml		D10707	5 x 50 ml			
D0436917		9 x 65 ml		D00715	5 x 25 ml			
DK0739		5 x 50 ml		D00716	5 x 10 ml			
DA1042		5 x 20 ml		D82911	10 x 50 ml			
DT1042		5 x 20 ml		D0439917	5 x 62,5 ml			
DE1842		5 x 20 ml		DK0742	5 x 50 ml			
Triglycerides, <i>GPO-PAP</i>	D98386B	1 x 1 L		DA0845	5 x 50 ml			
	D08388	4 x 250 ml		DT1045	4 x 62,5 ml			
	D00389	5 x 100 ml		DE1845	4 x 62,5 ml			
	D96388	5 x 50 ml	Urea, <i>Urease/colorimetric</i>	402999	5 x 100 ml			
	D00390	5 x 25 ml		413925	6 x 25 ml			
	D98390	5 x 10 ml		Uric Acid AOX, <i>Enzymatic, colorimetric</i>	D94710	5 x 100 ml		
	D81911	10 x 50 ml			D98714	5 x 50 ml		
	D0438917	9 x 65 ml			D00719	5 x 25 ml		
	DK0740	5 x 50 ml			D00720	5 x 10 ml		
	DA0843	5 x 50 ml			D84911	10 x 50 ml		
	DT1043	4 x 50 ml			D0440917	5 x 62,5 ml		
	DE1843	10 x 50 ml			DK0743	5 x 50 ml		
					DA0846	5 x 50 ml		
		DT1046			4 x 62,5 ml			
		DE1846			8 x 62,5 ml			

	REF	CONT
Uric Acid TBHBA, <i>Enzymatic, colorimetric</i>	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 <i>5-Br-PAPS</i>	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

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		D08582	12 x 5 ml	
Diacon P	D98482	12 x 5 ml	Diacon Urine Level 2	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	Y04706	6 x 2 ml
Diacon Lipids High	D11487	3 x 3 ml	(3 levels)			
	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

EC DECLARATION OF CONFORMITY

We



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2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed addendum "Other Products (Urine Strips), Rev.05 (1 page)", classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Urine Strips)

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

CE marking has been carried out following the procedure referred to in Annex III of the aforesaid Directive.

This declaration is valid until 2019-04-12.

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DI Marlene Ramsey
Managing Director

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Addendum to the Declaration of Conformity for Other Products (Urine Strips)

URINE STRIPS Strips

REF	CONT
G04001	100 strips
G04002	100 strips
G04002A	50 strips
G11002MC	50 strips
G135003	50 strips
G04003A	100 strips
G04004	100 strips
G04005	50 strips
G04004SG	100 strips
G11008	50 strips
G04009	100 strips
G13510C	50 strips
G04010C	100 strips
G11010C	150 strips
G04011	100 strips
G11011	150 strips

Strips with Mesh Technology

REF	CONT
Z10010ME/BOX	100 strips

Urine Controls

REF	CONT
798001	2x12 mL

Urine Comby Control
urine strip & analyser control (pos & neg)

