

EC Declaration Of Conformity



TRIMERO Diagnostics, SL
c. València 558, 4t 2a - 08026 Barcelona (Spain)
+34 93 244 8679 - www.3diag.com



KITS for the determination of Plasma Proteins on Clinical Chemistry analysers (Turbidimetry)

The Manufacturer,

TRIMERO Diagnostics SL - c. València, 558, 4º 2ª - 08026 Barcelona (Spain)

declares under his responsibility that the products:

Product:	κλoneus[®] FLC		Basic UDI-DI:	843447701-FLC9V
Models:	κλoneus[®] - S-FLC-K - TIA Kit	Ref. TD-42510-K	UDI-DI:	08434477301339
	κλoneus[®] - S-FLC-L - TIA Kit	Ref. TD-42510-L	UDI-DI:	08434477301346
	κλoneus[®] - U-FLC - TIA Kit	Ref. TD-42510-U	UDI-DI:	08434477301353
Product:	3diag- B2m		Basic UDI-DI:	843447702-B2M7V
Models:	3diag - B2m - TIA Kit	Ref. TD-42535	UDI-DI:	08434477302107
	3diag - U- B2m - TIA Kit	Ref. TD-42535-U	UDI-DI:	08434477302114
Product:	3diag- C1q		Basic UDI-DI:	843447703-C1Q8J
Model:	3diag - C1q - TIA Kit	Ref. TD-42555	UDI-DI:	08434477303135
Product:	3diag- C5		Basic UDI-DI:	843447704-C5GE
Model:	3diag - C5 - TIA Kit	Ref. TD-42575	UDI-DI:	08434477304149
Product:	3diag- C1In		Basic UDI-DI:	843447705-C1INZR
Model:	3diag - C1In - TIA Kit	Ref. TD-42595	UDI-DI:	08434477305061
Product:	3diag- CysC		Basic UDI-DI:	843447706-CYSC8L
Models:	3diag - CysC - TIA Kit	Ref. TD-42615	UDI-DI:	08434477306105
	3diag - U- CysC - TIA Kit	Ref. TD-42615-U	UDI-DI:	08434477306075
Product:	3diag- HPX		Basic UDI-DI:	843447707-HPXDX
Model:	3diag - HPX - TIA Kit	Ref. TD-42635	UDI-DI:	08434477307072
Product:	3diag- IgD		Basic UDI-DI:	843447708-IGDCC
Model:	3diag - IgD - TIA Kit	Ref. TD-42655	UDI-DI:	08434477308130

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Product:	3diag- RBP		Basic UDI-DI:	843447709-RBPED
Models:	3diag – RBP - TIA Kit	Ref. TD-42675	UDI-DI:	08434477309076
	3diag – U-RBP - TIA Kit	Ref. TD-42675-U	UDI-DI:	08434477309083
Product:	3diag- sTfR		Basic UDI-DI:	843447710-STFR95
Model:	3diag – sTfR - TIA Kit	Ref. TD-42694	UDI-DI:	08434477310096
Product:	3diag- FB		Basic UDI-DI:	843447712-FBHC
Model:	3diag – FB - TIA Kit	Ref. TD-42725	UDI-DI:	08434477312106
Product:	3diag- TLC/ KL		Basic UDI-DI:	843447711-TLCCG
Models:	3diag – KAP - TIA Kit	Ref. TD-42775	UDI-DI:	08434477311093
	3diag – U-KAP - TIA Kit	Ref. TD-42775-U	UDI-DI:	08434477311116
	3diag – LAM - TIA Kit	Ref. TD-42795	UDI-DI:	08434477311109
	3diag – U-LAM - TIA Kit	Ref. TD-42795-U	UDI-DI:	08434477311123
Product:	3diag- A1m		Basic UDI-DI:	843447715-A1M93
Model:	3diag – U-A1m - TIA Kit	Ref. TD-42835	UDI-DI:	08434477315053
Product:	3diag- SAA		Basic UDI-DI:	843447718-SAADK
Model:	3diag – SAA - TIA Kit	Ref. TD-42895	UDI-DI:	08434477318061

Comply with the essential requirements of Annex I of the 98/79/CE Directive on *In Vitro* Diagnostic Medical Devices, that are applicable to them.

Product Classification: **IVDMD, neither of Annex II, nor of Self-diagnosis.**

Assessment Conformity: **In accordance with Annex III of 98/79/CE Directive.**

TRIMERO Diagnostics SL

Barcelona, May 20th, 2022

Joan Carles Gómez - General Manager