

EC Declaration of Conformity



TRIMERO Diagnostics, SL
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Products for the determination of Light Chains (Bound and Free)

The Manufacturer,

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

declares under his responsibility that the products:

3diag - KAP - TIA KIT	REF TD-42775	Kappa Light Chains (B&F) - KIT - for Turbidimetry
3diag - U-KAP - TIA KIT	REF TD-42775-U	Kappa Light Chains (B&F) - Urine - KIT - for Turbidimetry
3diag - KAP - TIA	REF TD-42771	Kappa Light Chains (B&F) - for Turbidimetry
3diag - LAM - TIA KIT	REF TD-42795	Lambda Light Chains (B&F) - KIT - for Turbidimetry
3diag - U-LAM - TIA KIT	REF TD-42795-U	Lambda Light Chains (B&F) - Urine - KIT - for Turbidimetry
3diag - LAM - TIA	REF TD-42791	Lambda Light Chains (B&F) - for Turbidimetry
3diag - KL - CAL SET	REF TD-42772	Light Chains (B&F) - Calibrators (5 lev.)
3diag - KL - CAL	REF TD-42792	Light Chains (B&F) - Calibrators (2 lev.)
3diag - KL - CONTROL	REF TD-42774	Light Chains (B&F) - Controls (2 lev.)
3diag - KL - CONTROL (x3)	REF TD-42773	Light Chains (B&F) - Controls (2 lev.) (3 un.)
3diag - U-KL - CAL SET	REF TD-42782	Light Chains (B&F) - Urine - Calibrators (6 lev.)
3diag - U-KL - CONTROL	REF TD-42793	Light Chains (B&F) - Urine - Controls (2 lev.)

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 3, 2021

Joan Carles Gómez - General Manager