

EC Declaration of Conformity



TRIMERO Diagnostics, SL
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κλoneus® Products for the determination of Free Light Chains

The Manufacturer,

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

declares under his responsibility that the products:

κλoneus® - S-FLC-K - 800 KIT	REF TD-42500-K	Free Light Chains Kappa - Serum - KIT - for <i>IMMAGE® 800</i>
κλoneus® - S-FLC-L - 800 KIT	REF TD-42500-L	Free Light Chains Lambda - Serum - KIT - for <i>IMMAGE® 800</i>
κλoneus® - U-FLC - 800 KIT	REF TD-42500	Free Light Chains - Urine - KIT - for <i>IMMAGE® 800</i>
κλoneus® - FLC - 800 CAL SET	REF TD-42501	Free Light Chains - Calibrators - for <i>IMMAGE® 800</i>
κλoneus® - FLC - 800 CONTROL	REF TD-42502	Free Light Chains - Controls - for <i>IMMAGE® 800</i>
κλoneus® - U-FLC - BNS KIT	REF TD-42505	Free Light Chains - Urine - KIT - for <i>BN™ Series</i>
κλoneus® - U-FLC-K - BNS KIT	REF TD-42505-K	Free Light Chains Kappa - Urine - KIT - for <i>BN™ Series</i>
κλoneus® - U-FLC-L - BNS KIT	REF TD-42505-L	Free Light Chains Lambda - Urine - KIT - for <i>BN™ Series</i>
κλoneus® - U-FLC - CAL-L	REF TD-42508	Free Light Chains - Urine - Low Calibrator
κλoneus® - U-FLC - CONTROL (2)	REF TD-42509	Free Light Chains - Urine - Controls (2) (3 lev.)
κλoneus® - S-FLC-K - TIA KIT	REF TD-42510-K	Free Light Chains Kappa - Serum - KIT - for Turbidimetry
κλoneus® - S-FLC-K - TIA	REF TD-42511-SK	Free Light Chains Kappa - Serum - for Turbidimetry
κλoneus® - S-FLC-L - TIA KIT	REF TD-42510-L	Free Light Chains Lambda - Serum - KIT - for Turbidimetry
κλoneus® - S-FLC-L - TIA	REF TD-42511-SL	Free Light Chains Lambda - Serum - for Turbidimetry
κλoneus® - U-FLC - TIA KIT	REF TD-42510-U	Free Light Chains - Urine - KIT - for Turbidimetry
κλoneus® - U-FLC-K - TIA	REF TD-42511-UK	Free Light Chains Kappa - Urine - for Turbidimetry
κλoneus® - U-FLC-L - TIA	REF TD-42511-UL	Free Light Chains Lambda - Urine - for Turbidimetry
κλoneus® - S-FLC-K - CAL-L SET	REF TD-42512-SK	Free Light Chains Kappa - Serum - Low Calibrators (6 lev.)
κλoneus® - S-FLC-L - CAL-L SET	REF TD-42512-SL	Free Light Chains Lambda - Serum - Low Calibrators (6 lev.)
κλoneus® - U-FLC - CAL SET	REF TD-42501-U	Free Light Chains - Urine - Calibrators (6 lev.)
κλoneus® - S-FLC-K - CONTROL	REF TD-42502-SK	Free Light Chains Kappa - Serum - Controls (3 lev.)
κλoneus® - S-FLC-L - CONTROL	REF TD-42502-SL	Free Light Chains Lambda - Serum - Controls (3 lev.)
κλoneus® - U-FLC - CONTROL	REF TD-42502-U	Free Light Chains - Urine - Controls (3 lev.)

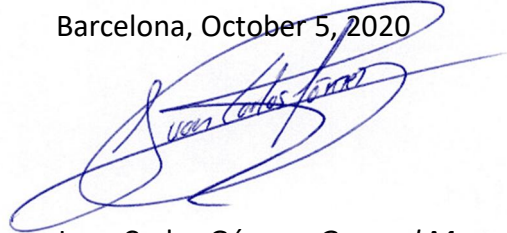
comply with the essential requirements of Annex I of the 98/79/CE Directive on *In Vitro* Diagnostic Medical Devices (IVDMD), that are applicable to them.

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, October 5, 2020



Joan Carles Gómez -*General Manager*