EC Declaration of Conformity



Products for the determination of Serum Amyloid A

The Manufacturer,

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

declares under his responsibility that the products:

3diag - SAA - 800 KIT	REF TD-42880	Serum Amyloid A - KIT - for IMMAGE® 800
3diag - SAA - TIA KIT	REF TD-42895	Serum Amyloid A - KIT - for Turbidimetry
3diag - SAA - TIA	REF TD-42891	Serum Amyloid A - for Turbidimetry
3diag - SAA - CAL SET	REF TD-42882	Serum Amyloid A - Calibrators (6 lev.)
3diag - SAA - CAL	REF TD-42892	Serum Amyloid A - Calibrator
3diag - SAA - CONTROL	REF TD-42883	Serum Amyloid A - 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, March 8, 2021

Joan Carles Gómez - General Manager