

EC Declaration of Conformity



TRIMERO Diagnostics, SL
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Products for the determination of C1q Complement

The Manufacturer,

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

declares under his responsibility that the products:

3diag - C1q - 800 KIT	REF TD-42540	C1q Complement - KIT - for <i>IMMAGE</i> [®] 800
3diag - C1q - 800	REF TD-42541	C1q Complement - for <i>IMMAGE</i> [®] 800
N Latex C1q Kit	REF TD-42550	C1q Complement - for <i>BN</i> [™] Series and <i>Atellica</i> [®] <i>NEPH 630</i>
3diag - C1q - BNs	REF TD-42545	C1q Complement - for <i>BN</i> [™] Series
3diag - C1q - TIA KIT	REF TD-42555	C1q Complement - KIT - for Turbidimetry
3diag - C1q - TIA	REF TD-42551	C1q Complement - for Turbidimetry
3diag - C1q - CAL SET	REF TD-42542	C1q Complement - Calibrators (6 lev.)
3diag - C1q - CAL	REF TD-42552	C1q Complement - Calibrator
3diag - C1q - CAL-L	REF TD-42558	C1q Complement - Low Calibrator
3diag - C1q - CONTROL	REF TD-42543	C1q Complement - Controls (2 lev.)
3diag - C1q - CONTROL (2)	REF TD-42559	C1q Complement - Controls (2 lev.)
3diag - C1q - CONTROL (BN)	REF TD-42548	C1q Complement - Controls (2 lev.) - for <i>BN</i> [™] Series

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 10, 2021

Joan Carles Gómez - General Manager