

# EC Declaration of Conformity



TRIMERO Diagnostics, SL  
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## Products for the determination of C5 Complement

The Manufacturer,

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

declares under his responsibility that the products:

<b>3diag - C5 - 800 KIT</b>	<b>REF</b> TD-42560	C5 Complement - KIT - for <i>IMMAGE® 800</i>
<b>3diag - C5 - 800</b>	<b>REF</b> TD-42561	C5 Complement - for <i>IMMAGE® 800</i>
<b>N C5 Kit</b>	<b>REF</b> TD-42570	C5 Complement - - for <i>BN™ Series and Atellica® NEPH 630</i>
<b>3diag - C5 - BNs</b>	<b>REF</b> TD-42565	C5 Complement - for <i>BN™ Series</i>
<b>3diag - C5 - TIA KIT</b>	<b>REF</b> TD-42575	C5 Complement - KIT - for Turbidimetry
<b>3diag - C5 - TIA</b>	<b>REF</b> TD-42571	C5 Complement - for Turbidimetry
<b>3diag - C5 - CAL SET</b>	<b>REF</b> TD-42562	C5 Complement - Calibrators (6 lev.)
<b>3diag - C5 - CAL-L</b>	<b>REF</b> TD-42578	C5 Complement - Low Calibrator
<b>3diag - C5 - CONTROL</b>	<b>REF</b> TD-42573	C5 Complement - Controls (2 lev.)
<b>3diag - C5 - CONTROL (x3)</b>	<b>REF</b> TD-42563	C5 Complement - Controls (2 lev.) (3 un.)
<b>3diag - C5 - CONTROL (2)</b>	<b>REF</b> TD-42579	C5 Complement - Controls (2 lev.)
<b>3diag - C5 - CONTROL (BN)</b>	<b>REF</b> TD-42568	C5 Complement - Controls (2 lev.) - for <i>BN™ Series</i>

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*