

EC Declaration of Conformity



TRIMERO Diagnostics, SL
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Products for the determination of Factor B (C3 Proactivator)

The Manufacturer,

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

declares under his responsibility that the products:

N C3Pa KIT	REF TD-42720	Factor B (C3 Proactivator) - for <i>BN™ Series and Atellica® NEPH 630</i>
3diag - FB - BNs	REF TD-42715	Factor B (C3 Proactivator) - for <i>BN™ Series</i>
3diag - FB - TIA KIT	REF TD-42725	Factor B (C3 Proactivator) - KIT - for Turbidimetry
3diag - FB - TIA	REF TD-42726	Factor B (C3 Proactivator) - for Turbidimetry
3diag - FB - CAL-H	REF TD-42727-H	Factor B (C3 Proactivator) - High Calibrator
3diag - FB - CAL-L	REF TD-42727-L	Factor B (C3 Proactivator) - Low Calibrator
3diag - FB - CONTROL-H	REF TD-42728-H	Factor B (C3 Proactivator) - High Control
3diag - FB - CONTROL-L	REF TD-42728-L	Factor B (C3 Proactivator) - Low Control

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*