

EC Declaration of Conformity



TRIMERO Diagnostics, SL
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Products for the determination of IgD Immunoglobulins

The Manufacturer,

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

declares under his responsibility that the products:

3diag - IgD - 800 KIT	REF TD-42640	IgD Immunoglobulins - KIT - for <i>IMMAGE</i> [®] 800
3diag - IgD - 800	REF TD-42641	IgD Immunoglobulins - for <i>IMMAGE</i> [®] 800
N Latex IgD KIT	REF TD-42650	IgD Immunoglobulins - for <i>BN</i> [™] Series and <i>Atellica</i> [®] NEPH 630
3diag - IgD - BNs	REF TD-42645	IgD Immunoglobulins - for <i>BN</i> [™] Series
3diag - IgD - TIA KIT	REF TD-42655	IgD Immunoglobulins - KIT - for Turbidimetry
3diag - IgD - TIA	REF TD-42651	IgD Immunoglobulins - for Turbidimetry
3diag - IgD - CAL SET	REF TD-42642	IgD Immunoglobulins - Calibrators (6 lev.)
3diag - IgD - CAL-L	REF TD-42658	IgD Immunoglobulins - Low Calibrator
3diag - IgD - CONTROL	REF TD-42643	IgD Immunoglobulins - Controls (2 lev.)
3diag - IgD - CONTROL (2)	REF TD-42659	IgD Immunoglobulins - Controls (2) (2 lev.)
3diag - IgD - CONTROL (BN)	REF TD-42648	IgD Immunoglobulins - 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, 10th May 2021

Joan-Carles Gómez
General Manager