



Dia.Pro  
**Diagnostic**  
Bio**Probes**

# EC DECLARATION OF CONFORMITY

|                                    |                                                                                                          |
|------------------------------------|----------------------------------------------------------------------------------------------------------|
| <b>MANUFACTURER</b>                | DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.<br>VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY |
| <b>PRODUCT</b>                     | <b>VCA IgM</b><br>CODE: <b>VCAM.CE</b> (96 tests)                                                        |
| <b>CLASSIFICATION</b>              | GENERAL IVD                                                                                              |
| <b>CONFORMITY ASSESSMENT ROUTE</b> | SELF CERTIFICATION                                                                                       |

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS  
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

|                        |                                                                                                                           |
|------------------------|---------------------------------------------------------------------------------------------------------------------------|
| <b>ISO CERTIFICATE</b> | UNE EN ISO 13485 N° 2013 11 0039 EN,<br>RELEASED BY AEMPS (AGENCIA ESPAÑOLA<br>DE MEDICAMENTOS Y PRODUCTOS<br>SANITARIOS) |
|------------------------|---------------------------------------------------------------------------------------------------------------------------|

|                                                                      |                                                                                      |
|----------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <b>PLACE &amp; DATE OF FIRST ISSUE</b>                               | MILANO – SEPTEMBER 2004                                                              |
| <b>PLACE &amp; DATE OF CURRENT ISSUE</b>                             | SESTO SAN GIOVANNI (MI) – MARCH 2019                                                 |
| <b>SIGNATURE</b><br>Legal Representative<br>Dr.ssa Fiorenza Scozzesi |  |

Rev: 05/2018