



Dia.Pro  
**D**iagnostic  
Bio**P**robes srl

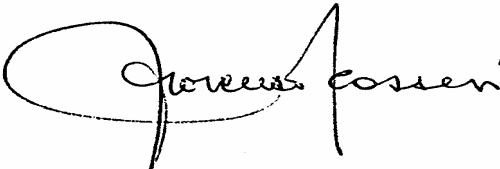
# DECLARATION OF CONFORMITY

|                                    |                                                                             |
|------------------------------------|-----------------------------------------------------------------------------|
| <b>MANUFACTURER</b>                | DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.<br>VIA COLUMELLA N° 31 - MILANO - ITALY |
| <b>EUROPEAN REPRESENTATIVE</b>     | NONE                                                                        |
| <b>PRODUCT</b>                     | CMV IgM – CODE CMVM.CE                                                      |
| <b>CLASSIFICATION</b>              | ANNEX II – LIST B                                                           |
| <b>CONFORMITY ASSESSMENT ROUTE</b> | ANNEX IV                                                                    |

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

**ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER  
THE PREMISES OF THE MANUFACTURER.**

|                            |                                                                                                                                                                                                                                                                      |
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| <b>STANDARDS APPLIED</b>   | ISO 9001:2000/ISO 13485:2000 //EN 1441:1997 //<br>EN ISO 14971:2000 // EN 375:2001 // ISO<br>15223:2000 // EN 980:1996+A1:1999+A2:2001 // EN<br>13612 :2002 // EN 13640 :2002 // EN<br>12286 :1998+A1 :2000 // EN 12287 :1999 // DL<br>172/2001 // IT. LAW N° 626/94 |
| <b>NOTIFIED BODY</b>       | MINISTRY OF HEALTH – SPAIN – n° 0318                                                                                                                                                                                                                                 |
| <b>(EC) CERTIFICATE(S)</b> | <ul style="list-style-type: none"><li>FULL QUALITY ASSURANCE SYSTEM<br/>in accordance with Annex IV(except Section 4) of<br/>Directive 98/79 EC, N° 2004 05 0442 CT,<br/>RELEASED BY EC NOTIFIED BODY N° 0318</li><li>EN-ISO 13485:2000 N°2003 12 2388 EN</li></ul>  |
| <b>START OF CE-MARKING</b> | MAY 2004                                                                                                                                                                                                                                                             |

|                                          |                                                                                      |
|------------------------------------------|--------------------------------------------------------------------------------------|
| <b>PLACE &amp; DATE OF ISSUE</b>         | MILANO – 05/2004                                                                     |
| <b>SIGNATURE</b><br>Legal Representative |  |