



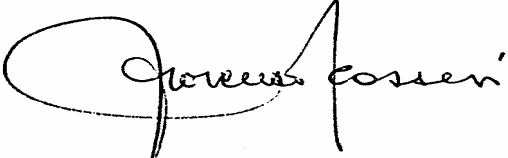
Dia.Pro  
**Diagnostic**  
Bio**Probes** srl

# 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>                     | H. Pylori IgM – CODE HPM.CE   |
| <b>CLASSIFICATION</b>              | NOT CLASSIFIED  |
| <b>CONFORMITY ASSESSMENT ROUTE</b> | AUTOCERTIFICATION   |

**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.**

|                            |   |
|----------------------------|---|
| <b>STANDARDS APPLIED</b>   | ISO 9001:2000/ISO 13485:2000 //EN 1441:1997 // EN ISO 14971:2000 // EN 375:2001 // ISO 15223:2000 // EN 980:1996+A1:1999+A2:2001 // EN 13612 :2002 // EN 13640 :2002 // EN 12286 :1998+A1 :2000 // EN 12287 :1999 // DL 172/2001 // IT. LAW N° 626/94 |
| <b>NOTIFIED BODY</b>       | MINISTRY OF HEALTH – SPAIN – n° 0318  |
| <b>(EC) CERTIFICATE(S)</b> | EN-ISO 13485:2000 N°2003 12 2388 EN   |
| <b>START OF CE-MARKING</b> | APRIL 2004  |

|  |  |
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| <b>PLACE &amp; DATE OF ISSUE</b>         | MILANO – 04/2004   |
| <b>SIGNATURE</b><br>Legal Representative |  |