



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

## DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA COLUMELLA N° 31 - MILANO - ITALY
<b>EUROPEAN REPRESENTATIVE</b>	NONE
<b>PRODUCT</b>	H. Pylori IgG – CODE HPG.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>	MARCH 2004

<b>PLACE &amp; DATE OF ISSUE</b>	MILANO – 03/2004
<b>SIGNATURE</b> Legal Representative	