



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>	HBsAg One – CODE SAG1.CE
<b>CLASSIFICATION</b>	ANNEX II – LIST A
<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.**

<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>	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM,( in accordance with Annex IV(except section IV) of Directive 98/79EC), N° 2003 12 0388 CT, RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• DESIGN CERTIFICATE N° 2003 12 0389 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>	JANUARY 2004

<b>PLACE &amp; DATE OF ISSUE</b>	MILANO – 01/2004
<b>SIGNATURE</b> Legal Representative	